Effectiveness of early orthopaedic treatment with headgear: a systematic review and meta-analysis

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Abstract: BACKGROUND Although the headgear appliance has been used extensively to correct antero-posterior discrepancies, its treatment effects have not yet been adequately assessed in an evidence-based manner. OBJECTIVE Aim of this systematic review was to assess the therapeutic and adverse effects of early headgear treatment from controlled clinical trials on human patients in an evidence-based manner. SEARCH METHODS An unrestricted electronic search of six databases from inception to December 2015. SELECTION CRITERIA Randomized and prospective non-randomized controlled trials assessing the effects of headgear treatment on human patients. DATA COLLECTION AND ANALYSIS After duplicate study selection, data extraction, and risk of bias assessment according to the Cochrane guidelines, random-effects meta-analyses of mean differences (MDs) and relative risks (RRs), including their 95% confidence intervals (CIs) were performed, followed by subgroup and sensitivity analyses. RESULTS A total of 18 unique studies with a total of 930 (56% male/44% female) patients were included. Headgear treatment was associated with a posterior translation of the anterior maxilla border in the short term, as seen by the mean annualized change in the SNA angle (MD = -1.63°/year; 95% CI = -2.20 to -1.06°/year; high quality evidence) compared to untreated patients. This effect was independent of the rotation of the palatal plane and the inclination of the upper incisors, while a proportional relationship with the initial discrepancy in SNA was seen. The clinical significance of this improvement diminished in the long term, although only limited evidence existed. Additionally, early headgear treatment might decrease the risk of dental trauma during the following years (RR = 0.34; 95% CI = 0.14 to 0.80; moderate quality evidence). Low quality evidence on the effect of headgear on the rotation of the palatal plane, the nasolabial angle, the occlusal outcome, and signs of temporomandibular disorders precluded robust assessments, due to risk of bias, inconsistency, imprecision, and small-study effects. CONCLUSIONS Based on existing trials, headgear is a viable treatment option to modify sagittal growth of the maxilla in the short term in Class II patients with maxillary prognathism. REGISTRATION PROSPERO (CRD42015029837). FUNDING None.

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Title Page

Effectiveness of early orthopedic treatment with headgear: a systematic review and meta-analysis

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Summary

Background: Although the headgear appliance has been used extensively to correct anteroposterior discrepancies, its treatment effects haven't yet been adequately assessed in an evidence-based manner.

Objective: Aim of this systematic review was to assess the therapeutic and adverse effects of early headgear treatment from controlled clinical trials on human patients in an evidence-based manner.

Search methods: An unrestricted electronic search of six databases from inception to December 2015.

Selection criteria: Randomized and prospective non-randomized controlled trials assessing the effects of headgear treatment on human patients.

Data collection and analysis: After duplicate study selection, data extraction, and risk of bias assessment according to the Cochrane guidelines, random-effects meta-analyses of Mean Differences (MDs) and Relative Risks (RRs),including their 95% Confidence Intervals (CIs) were performed, followed by subgroup and sensitivity analyses.

Results: A total of 18 unique studies with a total of 930 (56% male / 44% female) patients were included. Headgear treatment was associated with a posterior translation of the anterior maxilla border in the short-term, as seen by the mean annualized change in the SNA angle (MD=-1.63°/year; 95% CI: -2.20 to -1.06°/year; high quality evidence) compared to untreated patients. This effect was independent of the rotation of the palatal plane and the inclination of the upper incisors, while a proportional relationship with the initial discrepancy in SNA was seen. The clinical significance of this improvement, diminished in the long-term, although only limited evidence existed. Additionally, early headgear treatment might decrease the risk of dental trauma during the following years (RR=0.34; 95% CI=0.14 to 0.80; moderate quality evidence). Low quality evidence on the effect of headgear on the rotation of the palatal plane, the nasolabial angle, the occlusal outcome, and signs of temporomandibular disorders precluded robust assessments, due to risk of bias, inconsistency, imprecision, and small-study effects.

Conclusions: Based on existing trials, headgear is a viable treatment option to modify sagittal growth of the maxilla in the short-term in Class II patients with maxillary prognathism.

Registration: PROSPERO (CRD42015029837)

Conflict of interest: None

Introduction

Rationale

Application of extraoral traction to the maxilla has been used for many decades in order to restrain or redirect growth in Class II patients, especially those with maxillary excess (1, 2). This inhibitory effect on maxillary anterior displacement has most often been achieved with the headgear appliance, which according to the direction of applied force can be divided into three categories: high-pull headgear (anchored at the upper back of the head), cervical headgear (anchored at the back of the neck), and combi-headgear (anchored at both sites).

Clinical investigations have demonstrated that the effects of headgear treatment are partly due to dental changes in the sagittal and vertical plane and partly due to skeletal changes. Headgear has been reported to effectively modify maxillary growth in both the sagittal and the vertical direction (3, 4), while rotation of the palatal plane and changes in the anterior face height have also been reported (3, 5, 6). Many authors cite headgear type, as well as the magnitude of force applied and the direction of pull as important effect-modifying factors to be considered (7).

Although the headgear appliance has been studied extensively and has gained widespread acceptance as an effective means of correcting anteroposterior discrepancies, its treatment effects have yet to be adequately assessed in an evidence-based manner. Previous systematic reviews on the subject either pooled headgear together with other appliances (8), assessed various Class II modalities without focusing on headgear and all its aspects (9, 10) or included retrospective clinical studies (11), which have been shown to be associated with bias (12). Furthermore, methodological issues like the inappropriate use of fixed-effect models (13), problematic interpretation of meta-analysis results (14), and no assessment of the quality of evidence with the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach (15) might affect the conclusions of these reviews.

Objectives

Aim of this systematic review was to assess the evidence from randomized and prospective non-randomized trials in humans, in order to investigate the effect of orthopedic treatment of Class II with extraoral traction delivered to the maxilla with headgear appliance and compare it to untreated Class II patients.

Materials and Methods

Protocol and registration

The protocol for this review was made *a priori* based on the PRISMA-P statement (16), registered in PROSPERO (CRD42015029837), and all *post hoc* changes were appropriately noted. This systematic review was conducted and reported according to Cochrane Handbook (17) and PRISMA statement (18), respectively.

Eligibility criteria

According to the PICOS (Participant-Intervention-Comparison-Outcome-Study design) schema, parallel randomized or prospective non-randomized trials comparing any type of headgear appliance to an untreated control group in human patients were included. Excluded were non-clinical studies, retrospective studies, and studies where headgear was combined with other appliances. Additionally studies with purely dental effects of headgear (including molar distalization, tooth retraction, anchorage reinforcement, etc) were excluded, as these fall out of this review's scope (Supplementary Table 1).

Information sources and literature search

A total of six electronic databases were searched systematically by one author (SNP) without any limitations from inception up to December 12th, 2015 (Supplementary Table 2). Four additional sources (Scopus, Google Scholar, ClinicalTrials.gov, and ISRCTN registry) were manually searched for additional trials or protocols by the same author. No limitations concerning language, publication year or publication status were applied. The reference and citation lists of the included trials and relevant systematic reviews were manually searched as well.

Study selection

The titles/abstracts of identified studies were screened by one author (SNP) with a subsequent duplicate independent checking of their full-texts for eligibility by four authors (SNP, EK, SM, LG), while conflicts were resolved by another author (AJ).

Data collection

Characteristics of included trials and numerical data were extracted independently by the same authors (SNP, EK, SM, LG) using pre-determined and piloted extraction forms. Piloting of the forms was performed during the protocol stage until over 90% agreement was reached. Missing or unclear information was requested by the trials' authors and raw data were requested from the authors of all included trials to eliminate baseline confounding and perform explorative analyses.

Risk of bias in individual trials

The risk of bias of the included randomized and non-randomized trials was assessed using Cochrane's risk of bias tool (17) and with the ACROBAT-NRSI (A Cochrane Risk Of Bias Assessment Tool: for Non-Randomized Studies of Interventions) tool (19), respectively. A main risk of bias assessment was included in the systematic review pertaining to the review's primary outcome.

Data synthesis

As the outcome of headgear therapy is bound to be affected by the design of the appliance and the patient's malocclusion, growth potential, and compliance, a random-effects model according to DerSimonian and Laird was deemed appropriate to encompass this variability (20). The Mean Difference (MD) and the Relative Risk (RR) with their corresponding 95% Confidence Interval (CI) were chosen as effect measures for continuous and binary outcomes, respectively. The Standardized Mean Difference (SMD) was chosen to pool similar cephalometric measurements of the inclination of the palatal plane (SN-NL and FH-NL), as well as similar cephalometric measurements of the sagittal position of the A point (Co-A and N-perpendicular-A). The Number Needed to Treat (NNT) was used to clinically translate the results of significant meta-analysis of binary outcomes.

Between-trial heterogeneity was quantified with the I^2 statistic, defined as the proportion of total variability in the results explained by heterogeneity, and not chance (21). The 95% Uncertainty Intervals (95% UI) (similar to CIs) around the I^2 were calculated using the non-central χ^2 approximation of Q (22). 95% Predictive Intervals (95% PrI) were calculated for meta-analyses of three trials or more, as they incorporate existing heterogeneity and provide a range of possible effects for a future clinical setting, which makes them crucial for the interpretation of random-effects meta-analyses (23). All analyses were run in Stata SE 10.0 (StataCorp, College Station, TX) by one author

(SNP). A two-tailed P-value of 0.05 was considered significant for hypothesis-testing, except for a 0.10 used for the test of heterogeneity and reporting biases, due to low power (24).

Risk of bias across studies

The overall quality of evidence (confidence in effect estimates) for each of the main outcomes was rated using the GRADE approach (15) by one author (SNP) and checked from three others (EK, SM, LG). For the included cephalometric outcomes, the GRADE assessment was based on the short-term effects directly after early phase 1 headgear treatment, as the majority of studies reported these. Additionally, cephalometric outcomes have been shown to be transient and their stability heavily dependent on the retention scheme. For the rest of included outcomes, which were non-cephalometric and patient-oriented in nature, the long-term effects after a subsequent phase 2 comprehensive fixed appliance treatment were assessed, as these are clinically more relevant. The minimal clinical important, large, and very large effects were conventionally defined (Supplementary Data). The produced forest plots were augmented with contours denoting the magnitude of the observed effects.

Additional analyses

In meta-analyses of at least five studies, possible sources of heterogeneity were planned *a priori* to be sought through pre-specified mixed-effects subgroup analyses/random-effects meta-regression with the Knapp-Hartung (25) adjustment. Indications of reporting biases (including small-study effects) were assessed for meta-analyses with ≥10 studies with Egger's linear regression test (26) and inspection of contour-enhanced funnel plots.

Sensitivity analyses

Sensitivity analyses were conducted for meta-analyses of at least 10 studies to assess their robustness according to the study design, the improvement of the GRADE classification, and any data transformations performed. Finally, a sensitivity analysis was conducted to check if the headgear-induced SNA reduction was due to anteroposterior translation of the A point (subspinale) or rather a cephalometric artifact due to a change in the inclination of the maxillary base or to a change in the inclination of the upper incisors.

Results

Study selection

A total of 800 and 30 papers were identified through the electronic and manual searches, respectively (Figure 1). After removal of duplicates and initial screening (Supplementary Table 3), 118 papers were judged against the eligibility criteria, leaving a final number of 47 included published papers. After collating multiple publications pertaining to the same trials, a total of 18 separate trials were included (Figure 1; Supplementary Table 3).

Study characteristics

The characteristics of the included trials can be seen in Tables 1-2. Out of the 18 included trials, five (28%) were randomized and the remaining 13 (72%) were prospective non-randomized trials. They included a total of 930 patients (with at least 479 male and 379 female patients) with mean ages ranging between 7.6 to 12.9 years. In nine studies (50%) a high-pull headgear, in five (28%) a cervical, and in three (17%) a combi-headgear was used. In one randomized study, either a high-pull or a cervical headgear was used, according to the initial mandibular plane angle of each patient. In almost all of the included studies (n=17; 94%) the inner bow of headgear was attached to the tubes of molar bands (n=8; 44%), various kinds of plates/biteplanes (n=6; 33%) or a combination of those (n=3; 17%), while the control group received no treatment.

One study compared a headgear-fixed appliance group to a group receiving only fixed appliance and is reported separately from the others to separate the pure effects of headgear from the effects of the fixed appliances.

The corresponding authors of all included trials (apart from two older studies) were contacted to request raw trial data. However, apart from three dissertations that already provided raw data as appendices (27-29), no additional data could be retrieved.

Risk of bias within studies

A summary of the risk of bias for all studies can be seen in Figure 2. The detailed risk of bias assessment for the included randomized and non-randomized trials can be found in Supplementary Table 4 and 5, respectively. Serious risk of bias was found in 4 of the 5 randomized trials for at least one domain and for multiple domains of all non-randomized trials. The most problematic domain for both randomized and non-randomized trials was the lack of

blinding for the outcome assessors. Domains that were also problematic for most non-randomized trials were confounding and unclear or problematic selection of participants into the study.

Results of individual studies and data synthesis

From the 18 studies included in the systematic review, three trials did not proceed to the phase of data synthesis, as they did not report complete outcome data and therefore, were excluded.

The results of the primary outcome and the six secondary outcomes can be seen in Table 3. As far as short-term annualized cephalometric effects are concerned, the early headgear treatment was associated with a significant reduction in the SNA angle (MD=-1.63°/year; 95% CI: -2.20 to -1.06°/year; Figure 3), a significant posterior rotation inclination of the palatal plane (SN-NL and FH-NL angles), and a significant backward repositioning of the anterior maxilla border (Co-A and Nperp-A distances), while no effect on the nasolabial angle was found.

As far as long-term cephalometric effects after a subsequent phase 2 fixed appliance treatment are concerned, headgear treatment was associated with a minimal reduction in the SNA angle (MD=-0.14°/year; 95% CI: -0.26 to -0.02°/year) and a considerable retraction of the anterior maxilla border (measured with Co-A and Nperp-A; SMD=-0.46/year; 95% CI: -0.75 to -0.17/year). Finally, headgear treatment was associated with a reduction in the risk of dental trauma during the phase 2 fixed appliance treatment (RR=0.34; 95% CI=0.14 to 0.80). The number needed to treat (NNT=9) indicated that an additional dental trauma incident during the fixed appliance phase would be avoided for every 9 patients that were treated early with headgear.

Regarding non-cephalometric outcomes, headgear treatment was associated with a statistically significant, but clinically irrelevant, reduction in the Peer Assessment Rating (PAR) index and a slight reduction in the incidence of dental trauma and temporomandibular joint pain, both of which were not statistically significant.

Additional outcomes that were reported from included studies, but which were not included in the protocol of this review can be seen in Supplementary Table 6. Headgear treatment was associated with reduced priority, difficulty, and duration for a subsequent comprehensive treatment with fixed appliances, although the overall treatment duration (for both phases) was longer. Additionally, no apparent effect of headgear treatment on either external apical root resorption or signs of temporomandibular disorders could be found. The single trial that compared headgear plus fixed appliances to fixed appliance alone reported no significant effect of headgear treatment on head posture after 11-12 months of treatment.

Risk of bias across studies

The assessment of reporting biases (including the possibility of publication bias) can be seen in Supplementary Figure 1. No signs of bias were found for the SNA angle (Egger's coefficient=-0.04; 95% CI=-5.25 to 5.17; P=0.986). However, significant signs of reporting bias were seen for the combined SN-NL & FH-NL analysis (Egger's coefficient=5.18; 95% CI=1.61 to 8.75; P=0.009), which indicated that small/imprecise studies tend to exaggerate the effects of headgear treatment (i.e. "small-study effects"). When looking at the most precise third of the available studies through a *post hoc* stratified analysis, a considerably smaller and clinically irrelevant effect of headgear treatment on the maxillary inclination was seen (Supplementary Figure 2).

Additional analyses

The investigation of possible sources of heterogeneity through subgroup analyses and meta-regressions indicated that no statistically significant modifying effects could be found regarding age, gender, force magnitude and appliance (bands or biteplanes) (Supplementary Table 7). However, increased posterior rotation of the maxilla was found for cervical headgear compared to combi-headgear or high-pull headgear (SMD of 1.50 compared to 0.87 and 0.11, respectively). Although the difference in the magnitude of the effects was clinically significant, no statistical significance was reached, presumably due to the small number of contributing studies.

Explorative analysis of the effect of baseline SNA on the treatment-induced annual SNA reduction among headgear patients based on re-analysis of raw trial data, revealed a statistically significant modifying effect (Supplementary Table 8; coefficient=-0.18; 95% CI= -0.25 to -0.10). Based on these data, stratified meta-analysis of the three trials with available raw data selecting patients with increasing SNA showed that the annual reduction in SNA compared to the no treatment group increases proportionally to the initial SNA discrepancy (Supplementary Table 9). This indicates that the skeletal effects of headgear might be more pronounced, when used in patients with an increased degree of maxillary prognathism.

GRADE assessment

The GRADE assessments for the cephalometric and non-cephalometric outcomes can be seen in Tables 4 and 5, respectively (details in Supplementary Table 10). The quality of the overall cephalometric evidence was very low in

all instances, due to the high risk of bias, inconsistency, and signs of reporting biases. The quality of overall evidence regarding the rest of the outcomes ranged from low to moderate, due to high risk of bias and imprecision originating from inadequate sample sizes.

Sensitivity analyses

When comparing the original analysis of SNA angle with an adjusted analysis that takes into account the change in the inclination of the palatal plane (SN-NL or FH-NL angle) and the change in the inclination of the upper incisors (1s-NL angle), no considerable difference could be found (Supplementary Figure 3). This supports the notion that the SNA reduction achieved by headgear corresponds to a true posterior translation of the A point (subspinale) and is not a cephalometric artifact.

Sensitivity analyses indicated that the results were relatively robust. Randomized trials reported more conservative headgear effects than non-randomized trials (0.53 and 1.04 difference in MDs and SMDs, respectively) and adjusted estimates from available raw trial data were more conservative than the rest of the data, these were not statistically significant (Supplementary Table 11).

Sensitivity analysis on the basis of improving the GRADE classification by eliminating all factors that might introduce bias (Supplementary Table 12) indicated that high quality evidence supports a reduction in SNA achieved by headgear. On the other side, the robustness of the effects of headgear on the inclination of the palatal plane was very poor and the effects were inconsistent in direction, and therefore, caution is warranted by their interpretation.

Discussion

Summary of evidence

This systematic review included 5 randomized and 13 non-randomized trials and a total of 930 patients. A considerable lack of evidence exists regarding the therapeutic effects of headgear, and especially long-term outcomes. Most trials are small non-randomized trials that investigate short-term cephalometric effects with serious limitations in their planning, conduct, and reporting.

As far as short-term effects are concerned, headgear treatment was associated with a more posterior position of the anterior maxillar border compared to untreated patients, as seen through both the SNA angle and the combined Co-A / Nperp-A distances. This could be interpreted as a modification of the maxillary sagittal growth resulting from the application of extraoral traction. Some authors consider the A point (subspinale) to be an unreliable anatomic landmark, which may be directly influenced from the labial inclination of the upper incisors (30-33) or from the rotation of the palatal plane (34-36). However, the explorative analysis of raw data (Supplementary Figure 3) indicated that there was little to no change in the SNA reduction by headgear, when the treatment changes in the incisor inclination or the rotation of the palatal plane during treatment were taken into account (original and adjusted MDs of -0.84 and -0.74, respectively; both $P<0.001$). This supports the notion that the effect of headgear might be due to a true change in the skeletal base, rather an artifact of cephalometric measurement. Additionally, the amount of headgear-induced reduction in the SNA angle was significantly associated with the baseline SNA angle (Supplementary Table 8), as can also been seen by the stratified meta-analyses according to baseline SNA (Supplementary Table 9). This seems to indicate that the skeletal effects of headgear treatment are more pronounced in patients with a marked maxillary prognathism. Finally, this might also explain some of the variability seen in the results of existing headgear trials, as increased SNA is rarely used as a criterion to recruit appropriate Class II patients for headgear treatment (mean baseline SNA ranging between 78.9° to 84.3° in the included trials).

Based on the results of the subgroup analyses (Supplementary Table 7), there was only a small variation in the headgear effect on the SNA angle among high-pull, cervical, and combi-headgear. This agrees in part with older retrospective data that reported no significant difference in the change in SNA angle between cervical and high-pull headgear (37, 38). Allthough Baumrind *et al*. (37), contrary to our results, reported greater SNA reduction with the high-pull headgear compared to the cervical headgear (average difference of 0.26° in SNA), this was not statistically significant, while the two groups were retrospective in nature and differed in baseline characteristics and treatment duration.

According to the results of this systematic review, the effect of headgear treatment on the inclination of the palatal plane (measured with the SN-NL and FH-NL angles) could not be robustly assessed, due to the very low quality of evidence. With a first reading, headgear treatment was associated with a considerable posterior rotation of the maxilla (SMD of 0.54; translated to a 0.60°/yr increase in the SN-NL angle) compared to the control group.

However, the amount of posterior rotation was associated with the direction of applied forces (Supplementary Table 7), as cervical headgear resulted in much greater rotation of the maxilla compared to high-pull headgear (SMDs of 1.50 and 0.11, respectively), even if this difference was not statistically significant, due to large heterogeneity and imprecision. Additionally, considerable signs of reporting bias ("small-study effects") were seen, as small and imprecise studies tended to report significantly exaggerated rotational changes of the palatal plane than larger and more precise studies (Supplementary Figure 2). In the light of the serious risk of bias of the contributing studies, the very low quality of evidence, and the fact that the sensitivity analysis contradicted the results of the original analysis, making evidence-based recommendations about the effect of headgear on the maxillary inclination not feasible at this time and further well-designed studies are needed.

Concerning long-term effects of headgear treatment after a subsequent phase 2 comprehensive appliance with fixed appliances, moderate quality evidence indicated that there may be little to no difference in the occlusal outcome (measured as an overall reduction in PAR scores) between patients treated early with headgear or not (Table 5). This indicates that an initial better occlusal outcome in patients directly after headgear treatment (MD=-5.30; 95% CI=-8.77 to -1.83; P=0.003; 1 year after treatment) is "blended out", during the subsequent years and no significant difference exists after the comprehensive treatment with fixed appliances (P=0.530).

As far as early headgear treatment as means of prophylaxis for dental trauma is concerned, moderate to low quality of evidence supports a protective role of headgear (Table 5). The magnitude of this effect ranges from moderate (RR=0.68 for the combined duration of phase 1 and phase 2 treatment) to large (RR=0.34 for the duration of phase 2 treatment) and should be interpretated by weighing the pros and cos for each specific patient individually. Although the mean cost for trauma rehabilitation is smaller for patients treated with headgear than untreated ones (19.7$ compared to 60.6$; almost exclusively minor traumata observed), it is still minor and comes nowhere near the average fees of an orthodontic treatment (39). Additionally, many factors have been reported to influence the incidence of dental trauma including patient sex, age, obesity, bullying, sports activities, as well oral factors like lip competence and overjet (40-42), although overjet was not found to be correlated with trauma in the two included trials (39, 43). Using the overall trauma prophylaxis effect (RR=0.68) to calculate the NNT for an average Class II patient (trauma risk=33.3%; average of included trials) or a high-risk basketball-playing patient [trauma risk=55.4% (44)], we would avoid an extra incidence of dental trauma for each 9 average patients or 6 high-risk patients treated early with headgear.

No apparent effect of headgear on the post-treatment incidence of temporomandibular joint pain could be identified (Table 3), which agrees with cross-sectional data (45). Although headgear had a slight protective role, lowering the risk of joint pain for both asymptomatic patients and patients with pre-treatment joint pain, this effect was not statistically significant. It has been suggested, that a backward translation of the maxilla through headgear, with the subsequent compensatory retraction of the mandible by the muscles can put distal pressure on the condyles and cause an anterior dislocation of the disc (46). However, this could not be confirmed from the results of this review, where a slight joint-protective effect (RR=0.54) was found by headgear [although this was was not comparable to the improvement seen by anterior repositioning of the mandible with functional appliances (47)].

Limited evidence on the long-term results of headgear treatment indicated that the initial skeletal improvement diminished somewhat after phase 2 comprehensive treatment for both the SNA angle (MDs of -1.63°/year and -0.14°/year in the short- and long-term, respectively) and the Co-A & Nperp-A distance (SMDs of -0.61/year and -0.46/year in the short- and long-term, respectively), but remained statistically significant. The stability of the headgear effect is an important issue that has been heavily debated. It has been reported that relapse occurs to headgear patients after treatment (48), which is dental in nature, and was more probable in patients without retention (42% of patients without retention and 32% of patients with retention).

Finally, the results of headgear treatment are heavily dependent on patient compliance, which was assessed only subjectively in a small number of the included trials. Studies that evaluated the duration of headgear wearing have indicated that most patients do not comply with their appliance-wearing recommendations, especially when asked to wear these for prolonged times (49), and that clinicians are poor judges of compliance levels (50, 51). As only subjective measurements of headgear compliance were available and these have been shown to be unreliable, future studies utilizing objective electronic compliance measurement methods (52) would be useful to establish a dose and response on headgear treatment.

Strengths and limitations

The strengths of this systematic review include the extensive unrestrictive literature search, the robust review procedures, and the use of raw trial data in the analyses. Finally, this review was registered *a priori*, did not include biased retrospective trials, provided quantitative data for all included studies, and assessed the quality of evidence with the GRADE approach, while the robustness of the results to of bias was checked through sensitivity analyses.

However, some limitations are also present in this study. First and foremost, this systematic review could potentially suffer from the "garbage in, garbage out" principle. This pertains to the fact that the quality of existing trials on headgear is problematic, while mainly non-randomized trials exist. This might potentially influence the magnitude and direction of observed effects (12, 53, 54). Furthermore, additional outcome data from trialists could not be obtained, apart from three trials with already-provided data. Moreover, the effect of headgear could not be assessed in conjunction with (a) growth stage, (b) inclination of the outer bows, (c) patient compliance, and (d) retention scheme, although originally planned. Finally, the limited number of included trials precluded robust assessments of heterogeneity, subgroup analyses, small-study effects and reporting biases for most of the outcomes.

Conclusions

Based on high quality evidence, headgear treatment is associated with a short-term reduction of the SNA angle, which is independent of measurement specifities of the subspinale and is proportional to the degree of the initial discrepancy in the SNA angle. Therefore, headgear might seem like a viable and effective treatment option for the management of Class II malocclusion with maxillary prognathism. Based on evidence of moderate quality, treatment with headgear might decrease the risk of dental trauma during the subsequent years, so this should be taken into account when planning the Class II treatment of patients in high risk of dental trauma. The effect of headgear on the maxillary rotation, the nasolabial angle, the reduction in PAR scores, and signs of temporomandibular disorders could not be robustly assessed, due to limited evidence of low quality.

Recommendations for further research

Parallel randomized controlled trials or well-designed prospective non-randomized trials with blinded outcome assessment are needed in order to robustly assess the effects of headgear treatment for Class II malocclusion, especially in the long-term. Primary focus should be thrown into objective measurements of therapeutic effects (like patient satisfaction and quality of life, the quality of final occlusion measured with the American Board of Orthodontics Objective Grading System, treatment duration, and relapse) or adverse effects (including effect on upper airways, signs of temporomandibular disorders, root resorption, oral discomfort, functional impairment, and cost of treatment).

Supplementary material

Supplementary material are available at European Journal of Orthodontics online.

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Figure legends

Figure 1. Flowdiagram for the identification and selection of studies.

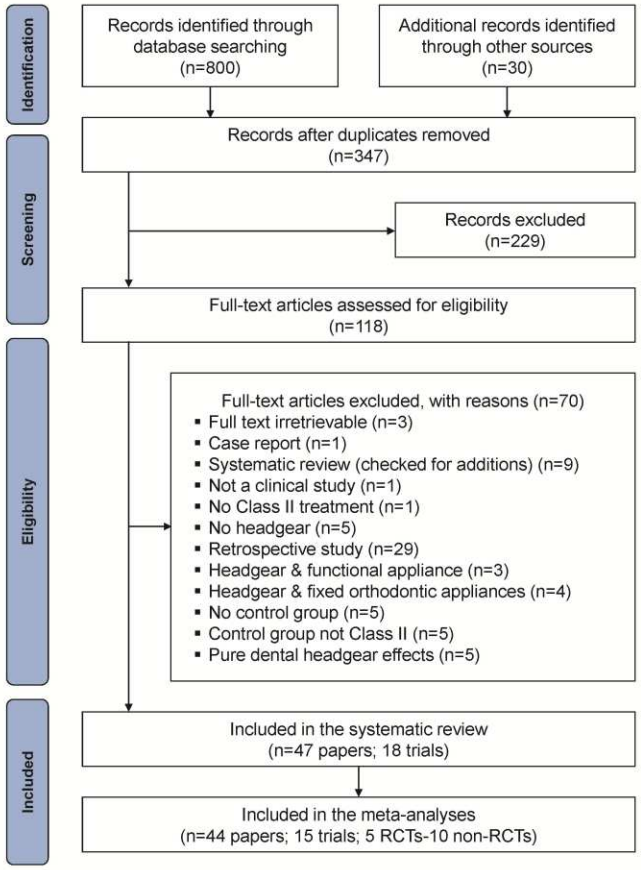

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Figure 2. Risk of bias in the included randomized (left) and non-randomized (right) trials. For the assessment of randomized trials (left), the colors indicate: low risk of bias (green), high risk of bias (red) or unclear risk of bias (yellow). For the assessment of non-randomized trials (right), the colors indicate: low risk of bias (green), moderate risk of bias (moderate), serious risk of bias (red), critical risk of bias (black) or unclear risk of bias, due to not adequate information (yellow). The numbers indicate possible domain of bias for non-randomized trials: 1. Bias due to confounding; 2. Bias in selection of participants into the study; 3. Bias in measurement of interventions; 4. Bias due to departures from intended interventions; 5. Bias due to missing data; 6. Bias in measurement of outcomes; 7. Bias in selection of the reported result.

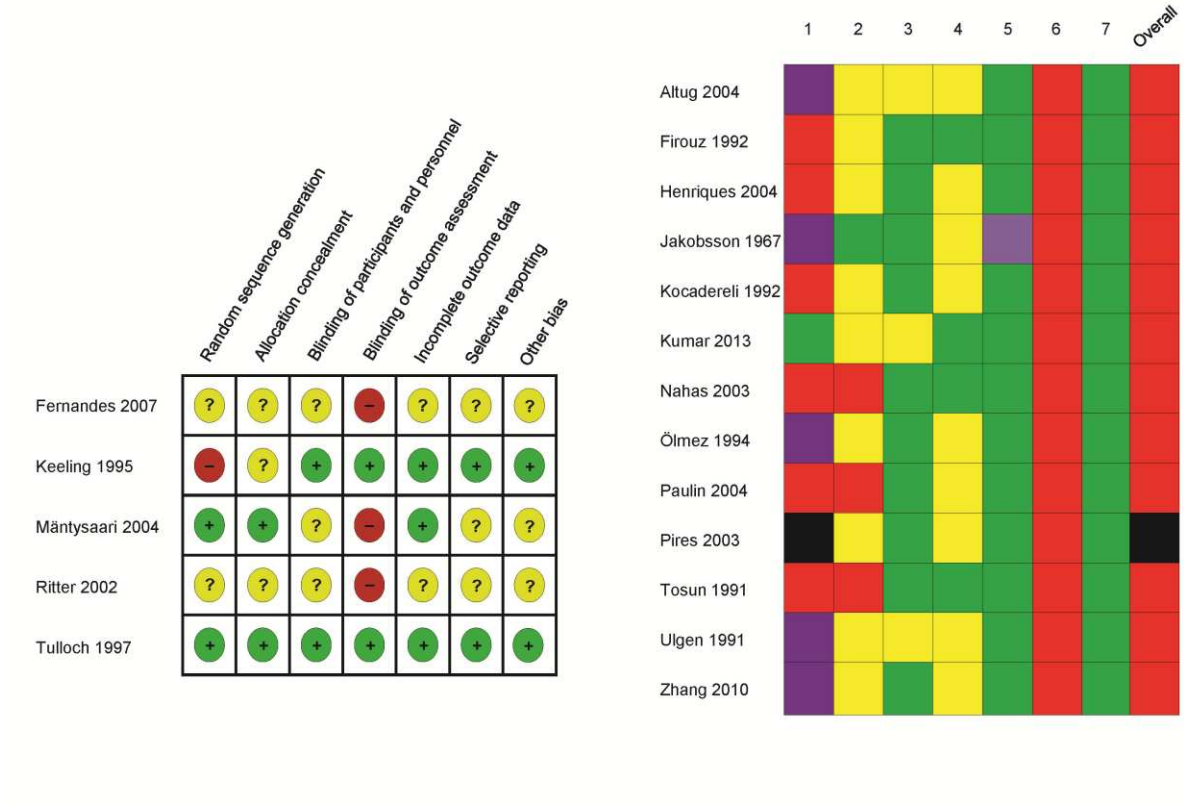

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Figure 3. Contour-enhanced forest plot for the meta-analysis of the primary outcome (difference of the annualized SNA angle change between the headgear and the control groups). Contours indicate increasing effect magnitude from the middle line-of-no-effect outwards (±1.7°, ±2.4°, ±3.7° used as cut-offs to indicate moderate, large, and very large effects). Studies to the left indicate that the SNA angle in headgear patients is reduced annually compared to untreated patients. MD, mean difference; CI, confidence interval; adj, adjusted effect estimate from regression of raw data; PrI, predictive interval.

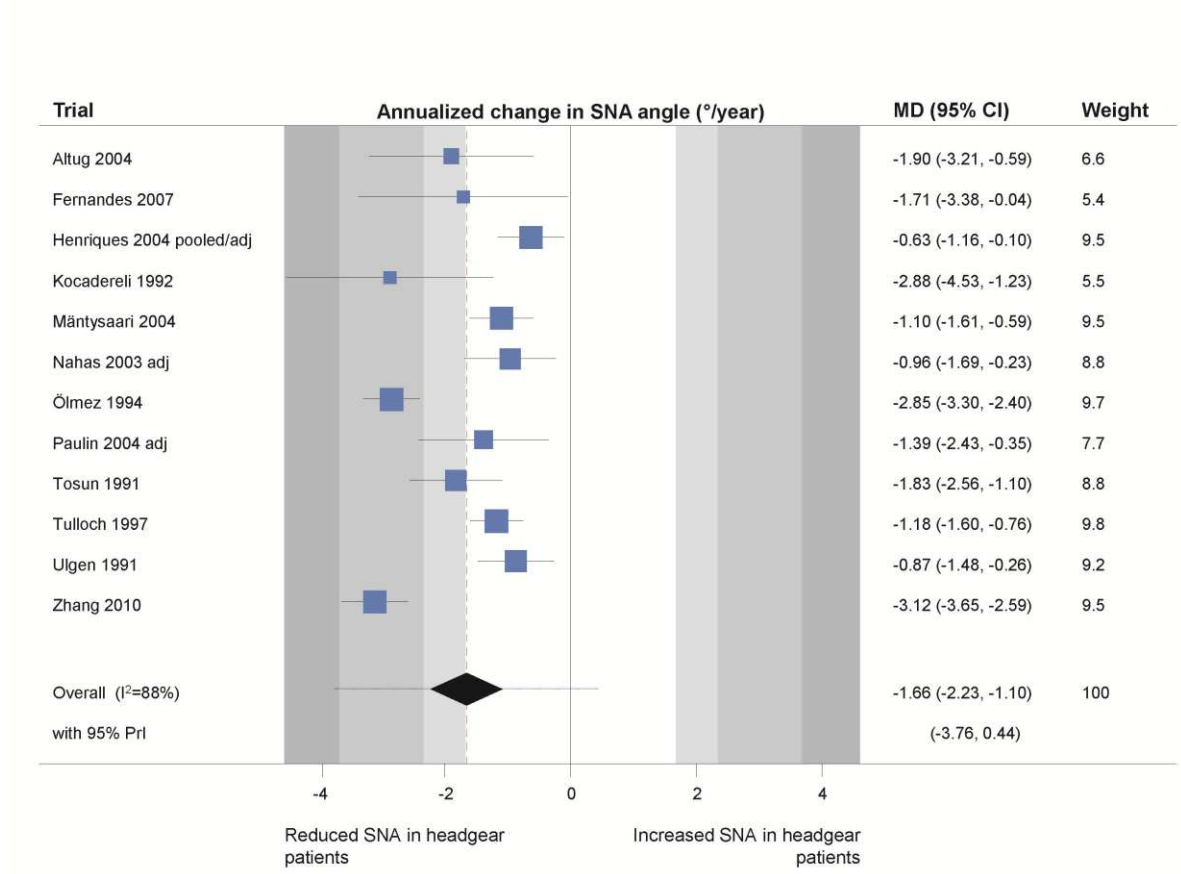

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Table 1. Design and patient characteristics of the included studies. M/F, male/female; yrs, years; uuCT, non-randomized clinical trial with unclear intervention and unclear control group; RCT, randomized controlled trial; pcCT; non-randomized clinical trial with prospective intervention and concurrent control group; uhCT; non-randomized clinical trial with unclear intervention and historical control group; phCT, non-randomized clinical trial with prospective intervention and historical control group; Exp, experimental group; Ctr, control group; Cl. II, Class II; OJ, overjet; OB, overbite; PPG, pubertal peak growth; HWR, hand-wrist radiograph; NR, not reported; CVM, cervical vertebrae maturation; LFH, lower face height; AOB, anterior open bite; MPA, mandibular plane angle.

No	Trial	Setting	Sample size (M/F)	Mean age (yrs)	Sagittal status	Vertical status	Growth status
	Headgear alone						
1	Altug 2004*	uuCT; university; Turkey	Exp: 30 (15/15) Ctr: 17 (7/10)	Exp: 12.9 Ctr: 12.6	Cl.II/1; OJ≥4.0mm	OB:2-5mm	90% after PPG (HWR)
2	Fernandes 2007**	RCT; university; Brazil	Exp: 19 (10/9) Ctr: 20 (13/7)	Exp: 10.0 Ctr: 9.9	Cl.II/1; Cl. II molar; OJ≥6mm; ANB≥ 4.0°	NR	prior to PPG (HWR&CVM)
3	Firouz 1992	pcCT; university; USA	Exp: 12 (NR) Ctr: 12 (NR)	NR	Cl.II; 1/2-1 cusp; interlabial gap≥ 2.0mm	Increased LFH	skel. age: 9.5-12.5 (HWR)
4	Henriques 2004	uhCT; university; Brazil	Exp1: 25 (13/12) Exp2: 25 (13/12) Ctr: 25 (13/12)	Exp1: 9.7 Exp2: 10.5 Ctr: 10.1	Cl.II/1	vertical growth pattern	NR
5	Jakobsson 1967**	pcCT; university; Sweden	Exp: 19 (NR) Ctr: 19 (NR)	Overall*: 8.5	Cl.II/1	NR	NR
6	Keeling 1995*,**	RCT; university; USA	Exp: 81 (46/35) Ctr: 74 (46/28)	Exp: 9.7 Ctr: 9.5	Cl.II; bil. 1/2 cusp (or equivalent); OJ>0mm; skel NR	OB>0mm	NR
7	Kocadereli 1992*	uuCT; university; Turkey	Exp: 14 (8/6) Ctr: 12 (4/8)	Exp: 9.9 Ctr: 9.9	Cl. II	NR	Growing
8	Mäntysaari 2004*	RCT; university; Finland	Exp/Ctr: 68 (40/28)	Exp/Ctr: 7.6	Cl.II tendency (20% full Cl.II); moderate crowding	NR	NR
9	Nahas 2003*,**	phCT; university; Brazil	Exp: 25 (10/15) Ctr: 31 (22/9)	Exp: 10.3 Ctr: 9.1	Cl.II/1	NR	NR
10	Ölmez 1994	pcCT; university; Turkey	Exp: 20 (11/9) Ctr: 20 (12/8)	Exp: 10.7 Ctr: 10.8	Cl.II/1	NR	NR
11	Paulin 2004*	phCT; university; Brazil	Exp: 15 (2/13) Ctr: 15 (8/7)	Exp: 8.4 Ctr: 6.0/9.0/12.0	Cl.II/1; vertical component	AOB; vertical pattern	NR
12	Pires 2003	uuCT; university; Brazil	Overall: 30 (20/10)	Overall: 10.0	Cl.II/1; maxillary excess	NR	NR
13	Ritter 2002	RCT; university; Brazil	Exp: 10 (7/3) Ctr: 10 (6/4)	Exp: 10.0 Ctr: 9.7	Cl.II; OJ>7mm	NR	prior to PPG
14	Tosun 1991	phCT; university; Turkey	Exp: 30 (10/20) Ctr: 24 (12/12)	Exp: 9.7 Ctr: 9.3	Cl.II/1; ANB≥ 4.0°	NR SN-Go/Gn 32°	NR
15	Tulloch 1997*,**	RCT; university; USA	Exp: 52 (31/29) Ctr: 61 (35/26)	Exp: 9.4 Ctr: 9.4	Cl. II; OJ≥7mm; skel NR	no extreme problems	1yr prior to PPG (HWR)
16	Ulgen 1991*	uuCT; university; Turkey	Exp: 10 (4/6) Ctr: 10 (5/5)	Exp: 9.0 Ctr: 9.5	Cl.II/1	NR	NR
17	Zhang 2010**	uuCT; university; China	Exp: 20 (10/10) Ctr: 20 (9/11)	Exp: 8.4 Ctr: 8.3	Cl.II/1	deepbite	growing patients (prior to PPG)

	Headgear plus fixed orthodontic appliances						
1	Kumar 2013	uuCT; university; India	Exp: 30 (30/0) Ctr: 25 (25/0)	Exp: 11.0 Ctr: 11.0	Cl.II; Cl. II molars; AND:4.5-6°	MPA 17-25°	Matched by CVM

* multiple published reports collated

** trial groups/data omitted as non-relevant

Table 2. Headgear characteristics of the included studies. HG, headgear; hr, hour; mo, month; Rad. magn., radiographic magnification; Ret, retention scheme; combi, combi-headgear; BiP, biteplane; cR, center of resistance; NR, not reported; Exp, experimental group; Ctr, control group; hp, high-pull headgear; M1, upper first molar; SS, stainless steel; TPA, transpalatal arch; Clin, clinical assessment of headgear compliance; Bd, bands; OP, occlusion plane; cer, cervical headgear.

AA	Trial	HG	Intraoral appliance	Outer bow inclination	Force/side; hrs wear (instructed)	Compliance	Active phase (mos)	Rad. magn.	Ret
	Headgear alone								
1	Altug 2004*	combi	BiP+ screw	upward (maxillary cR)	900gm; NR	NR	Exp: 6.0 Ctr: 12.0	NR	NR
2	Fernandes 2007**	hp	BiP	upward (M1 furcation)	400gm; 10hrs/day	NR	Exp: 12.0 Ctr: 12.0	NR	NR
3	Firouz 1992	hp	0.032x0.032“ SS welded TPA	parallel; furcation of M1	500gm; 12hrs/day	Diary & Clin	Exp: 6.0 Ctr: NR	NR	NR
4	Henriques 2004	hp	Exp1: BiP + screw Exp2: Bd	upwards (45° to OP)	350-500gm; 14-16hrs/day	Clin	Exp1: 16.9 Exp2: 15.8 Ctr: 16.2	Exp: 6%-9.8% Ctr: 6%	half of the active phase (nights)
5	Jakobsson 1967**	cer	Bd	NR	13-14hrs	NR	Exp: 18.0	NR	NR
6	Keeling 1995*,**	cer or hp (MPA≤ or >40°)	Bd & BiP	slightly upward	454gm; 14hrs/day	Clin	Exp: 25.2 Ctr: 26.4	NR	10hrs/day
7	Kocadereli 1992*	combi	Bd & BiP	NR	up to 500gm; 16-18hrs/day	NR	Exp: 12.1 Ctr: 10.8	NR	NR
8	Mäntysaari 2004*	cer	Bd	10° upward & expanded	350-500gm; 8-10hrs/day	NR	Exp/Ctr: 16.2	NR	NR
9	Nahas 2003*,**	hp	Bd	upward (M1 furcation)	400gm; 15hrs/day	Clin	Exp: 19.0	Exp: 9.8%/10.9% Ctr: 9.8%	NR
10	Ölmez 1994	hp	BiP	40° upwards	300gm	NR	Exp: 6.0 Ctr: 6.0	NR	NR
11	Paulin 2004*	hp	Thurow (BiP with crib)	(NR/upward)	400gm; 6 mos 14hrs/day & 6 mos 10hrs/day	NR	Exp: 12.00	Exp: 10.0% Ctr: 9.8%	NR
12	Pires 2003	hp	Exp1: BiP + screw (force anterior) Exp2: BiP + screw (force posterior)	(NR/upward) Exp1: at M1 Exp2: 20°; maxillary cR	500-700gm; >20hrs/day	NR	Exp1: 14.7 Exp2: 15.0 Ctr: 8.6	NR	NR
13	Ritter 2002	hp	BiP	(NR/upward posterior bent)	400gm; 8hrs/day	NR	Exp/Ctr: 12.0	NR	NR
14	Tosun 1991	hp	Bd	15° downwards	400-600gm; 16hrs/day	NR	Exp: 9.9 Ctr: 18.0	NR	3mos (nights)
15	Tulloch 1997*,**	combi	Bd	supershort outer bow; ending mesial to M1	227-283gm; at night	Diary & Clin	Exp: 15.0 Ctr: 15.0	Compared to Keeling 1995	some continued Tx

16	Ulgen 1991*	cer	Bd	NR	500-600gm; 13-14hrs/day	NR	Exp: 23.4 Ctr: 22.4	NR	NR
17	Zhang 2010**	cer	Bd	20° upwards & expanded	450gm; 12hrs/day	NR	Exp: 18.2 Ctr: 16.8	NR	NR
	Headgear plus fixed orthodontic appliances								
1	Kumar 2013	cer	Fixed appliances	15° upwards	350gm; 14-16hrs/day	Diary & Clin	Exp: 12.0 Ctr: 11.0	NR	NR

* multiple published reports collated
** trial groups/data omitted as non-relevant

Table 3. Details of the performed meta-analyses. CI, confidence interval; PrI, predictive interval; UI, uncertainty interval; Ph1, phase 1 (headgear treatment/observation); MD, mean difference; SMD, standardized mean difference; yr, year; PAR, peer assessment review; RR, relative risk; Ph2, phase 2 (fixed appliance treatment following headgear treatment/ observation).

Outcome	Timepoint	Studies	Metric	Effect (95% CI)	P	95% PrI	I^2 (95% UI)	t^2
Ph1								
SNA	after Ph1	12*	MD	-1.63 (-2.20,-1.06)	<0.001	-3.76, 0.44	88% (81%, 92%)**	0.80
SN-NL & FH-NL	after Ph1	12*	SMD	0.54 (0.09, 1.00)	0.019	-1.17, 2.26	91% (87%, 93%)***	0.54
	after Ph1+1yr	1	SMD	-0.18 (-0.48, 0.12)	0.235	-	-	-
Co-A & Nperp-A	after Ph1	8*	SMD	-0.61 (-0.95, -0.26)	0.001	-1.69, 0.48	75% (40%, 86%)**	0.17
Nasolabial angle	after Ph1	4*	MD	0.57 (-0.58, 1.72)	0.329	-1.95, 3.10	0% (0%, 68%)	0
	after Ph1+4yr	1	MD	0.55 (-0.45,1.55)	0.280	-	-	-
	after Ph1+8yr	1	MD	0.06 (-0.43, 0.55)	0.809	-	-	-
PAR index	after Ph1+1yr	1	MD	-5.30 (-8.77, -1.83)	0.003	-	-	-
	after Ph1+8yrs	1	MD	0.26 (-2.91, 3.43)	0.872	-	-	-
	after Ph1+13yrs	1	MD	-1.96 (-6.04, 2.12)	0.347	-	-	-
New incisor trauma	during Ph1	2	RR	0.80 (0.42, 1.49)	0.475	-	0% (-)	-
Joint pain; initially none	after Ph1	1	RR	0.54 (0.23, 1.25)	0.149	-	-	-
Joint pain; initially existing	after Ph1	1	RR	0.85 (0.48, 1.49)	0.561	-	-	-
Ph1 followed by Ph2								
SNA	after Ph2	1	MD	-0.14 (-0.26,-0.02)	0.027	-	-	-
SN-NL & FH-NL	-	-	-	-	-	-	-	-
Co-A & Nperp-A	after Ph2	2	SMD	-0.46 (-0.75, -0.17)	0.002	-	22% (-)	-
Nasolabial angle	after Ph2	1	MD	0.46 (-0.17, 0.61)	0.282	-	-	-
PAR index	after Ph2	2	MD	-0.69 (-2.83, 1.46)	0.530	-	0% (-)	-
New incisor trauma	during Ph2	2	RR	0.34 (0.14, 0.80)	0.014	-	0% (-)	-
	start Ph1-end Ph2	1	RR	0.68 (0.39, 1.17)	0.159	-	-	-
Joint pain; initially none	-	-	-	-	-	-	-	-
Joint pain; initially existing	-	-	-	-	-	-	-	-

* Pooled trial arms included.

** High heterogeneity identified, which could not be explained by subgroup analyses; however, it might affect only the precise estimation of the effect magnitude, not our decision about the direction of headgear's effect (i.e. all studies lie on the same side of the forest plot).

*** High heterogeneity identified, which could not be explained by subgroup analyses and could not be alleviated by excluding one or two imprecise studies. Heterogeneity could influence our decision about the direction of the headgear's effect (i.e. all studies on both sides of the forest plot). Some variation across studies can be explained by small-study effects (i.e. small/imprecise studies show exaggerated headgear effects). Caution is warranted in the interpretation of this outcome.

Table 4. GRADE summary of findings table for the main outcomes of the systematic review directly after treatment with headgear (phase 1). CI, confidence interval; HG, headgear; yr, year; MD, mean difference; SD, standard deviation; SMD, standardized mean difference.

Patients: receiving treatment for Class II malocclusion						
Settings: university clinics (Brazil, China, Finland, Sweden, Turkey, USA)						
Intervention: extraoral traction with the headgear appliance						
Comparison: no treatment						
		Anticipated absolute effects				
Outcomes, no of participants (studies)	**Relative effects (95% CI)**	**Observation**	**HG**	**Difference**	**Quality of the evidence (GRADE)**	**What happens**
SNA angle Follow-up: 0.5-2.0 yrs 607 patients (12 studies)	MD -1.63 (-2.20 to -1.06)	0.33°/yr increase	-	1.30°/yr decrease (0.73 to 1.87 decrease)	⊖⊖⊖⊖ very low[a,b,c] risk of bias and inconsistency	Probably decreases the SNA angle
SN-NL & FH-NL angle (translated to SN-NL; mean SD 1.12) Follow-up: 0.5-2.1 yrs 667 patients (12 studies)	SMD 0.54 (0.09 to 1.00)	0.16°/yr Increase	-	0.60°/yr increase (0.10 to 1.12 increase)	⊖⊖⊖⊖ very low[a,b,d] risk of bias, inconsistency, and reporting bias	Probably increases the SN-NL angle
Co-A & Nperp-A distance (translated to Nperp-A; chosen SD 1.17) Follow-up: 0.5-1.6 yrs 427 patients (8 studies)	SMD -0.61 (-0.95 to -0.26)	2.11mm/yr increase	-	0.71mm/yr decrease (0.30 to 1.11 decrease)	⊖⊖⊖⊖ very low[a,b] risk of bias and inconsistency	Probably decreases the Nperp-A distance
Nasolabial angle Follow-up: 1.3-2.0 yrs 287 patients (4 studies)	MD 0.57 (-0.58 to 1.72)	1.38°/yr increase	-	1.95°/yr increase (0.80 to 3.10 increase)	⊖⊖⊖⊖ very low[a] risk of bias	There may be little or no difference in nasolabial angle

[a]Starts from "low", due to the vast inclusion of non-randomized studies. Further downgraded by one, due to serious risk of bias from serious methodologic limitations.
[b]High heterogeneity, which could not be explained by subgroup analysis, while our confidence regarding decision is affected by it (trials on both sides of the forest plot).
[c]Signs of dose-response effectiveness (increased maxillary growth retardation with increased baseline discrepancy) and robustness after elimination of confounding (adjusted and unadjusted estimates were very similar) were found. However, we did not upgrade, as risk of bias and inconsistency exist.
[d]Signs of reporting bias (small-study effects) identified through Egger test. Small/imprecise studies tend to report greater treatment effects for headgear.

Table 5. GRADE summary of findings table for the main outcomes of the systematic review after treatment with headgear (phase 1) and after a subsequent fixed appliance treatment (phase 2).
CI, confidence interval; HG, headgear; PAR, peer assessment rating; yr, year; MD, mean difference; RR, relative risk; TMJ, temporomandibular joint; Ph1, phase 1 (headgear treatment/observation); Ph2, phase 2 (fixed appliance treatment following headgear treatment/ observation).

Patients: receiving treatment for Class II malocclusion						
Settings: university clinics (Brazil, China, Finland, Sweden, Turkey, USA)						
Intervention: extraoral traction with the headgear appliance (phase 1) followed by a subsequent comprehensive treatment with fixed orthodontic appliances (phase 2)						
Comparison: no treatment/observation (phase 1) followed by a subsequent comprehensive treatment with fixed orthodontic appliances (phase 2)						
		Anticipated absolute effects				
Outcomes **Follow-up** **No of participants (studies)**	**Relative effects (95% CI)**	**Observation**	**HG**	**Difference**	**Quality of the evidence (GRADE)**	**What happens**
PAR reduction (Ph 2) Follow-up: 3.8-4.8 yrs 240 patients (1 study)	MD -0.69 (-2.83 to 1.46)	19.55 points reduction	-	20.24 points reduction (18.1 to 22.4 points reduction)	⊕⊕⊕⊖ moderate[a] risk of bias	There may be little or no difference in PAR reduction
Incidence of dental trauma (Ph2) Follow-up: 1.7-2.5 yrs 220 patients (2 studies)	RR 0.34 (0.14 to 0.80)	17.2%	5.8% (2.4 to 13.8)	11.4% fewer patients (3.4 to 14.8 fewer)	⊕⊕⊕⊖ moderate[a] risk of bias	Probably decreases the incidence of dental trauma
Incidence of dental trauma (start Ph1-end Ph2) Follow-up: 4.8 yrs 140 patients (1 study)	RR 0.68 (0.39 to 1.17)	33.3%	22.6% (13.0 to 39.0)	10.7% fewer patients (20.3 fewer to 5.7 more)	⊕⊕⊖⊖ low[a, b] risk of bias and imprecision	May decrease the incidence of dental trauma
Incidence of new TMJ pain (Ph1) Follow-up: 2.1 yrs 83 patients (1 study)	RR 0.54 (0.23 to 1.25)	28.9%	15.6% (6.6 to 36.1)	13.3% fewer patients (22.3 fewer to 7.2 more)	⊕⊕⊖⊖ low[a, b] risk of bias and imprecision	May decrease the incidence of TMJ pain
Incidence of TMJ pain In patients with existing pain (Ph1) Follow-up: 2.1 yrs 48 patients (1 study)	RR 0.85 (0.48 to 1.49)	54.5%	46.3% (26.2 to 81.2)	8.2% fewer patients (28.3 fewer to 26.7 more)	⊕⊕⊖⊖ low[a, b] risk of bias and imprecision	May eliminate existing TMJ pain

[a]Downgraded by one point, due to high risk of bias in one randomized trial.
[b]Downgraded by one point, due to inadequate sample; the 95% CI includes both the null effect and large effect values, which indicates imprecision.

Supplementary Material

Effectiveness of early orthopedic treatment with headgear: a systematic review and meta-analysis

Supplementary Data. Additional details of the review's methodology.

Data transformations

- Data from studies reporting pre- and post-treatment data for the experimental and control groups, but not treatment-induced changes were transformed to increments, appropriately [Higgins and Green, 2011]. The pre-post correlations were calculated for each outcome and each group separately from the available raw data. The following pre-post correlations were adopted: 0.88 (sagittal skeletal variables - headgear); 0.96 (sagittal skeletal variables - control); 0.75 (sagittal soft-tissue variables - headgear); 0.78 (sagittal soft-tissue variables - control); 0.04 (PAR index - headgear); 0.01 (PAR index - control).
- Data reported as medians and interquartile ranges were assumed to be non-normal only due to small sample of the corresponding trial and were transformed to means and Standard Deviations (SDs).
- All cephalometric outcomes were converted to annualized changes in the headgear and control group according to the mean treatment/observation duration.
- Multiple intervention groups within included trials were pooled prior to meta-analysis of the overall treatment effects appropriately, in order to avoid double-counting the control patients and introducing bias. The pooled trial estimates were used for the overall treatment effects and sensitivity analyses the unpooled estimates were used for the investigation of sources of heterogeneity.
- Linear cephalometric measurements were planned to be transformed to a common scale across included trials by using the reported magnification factors of each study. This was rendered however void, as standardized effect sizes (which are not absolute, but rather relative measures

based on the pooled SD of the trial) were used in the final analysis to combine two similar linear measurement.

Effect magnitude and sample size calculations

The minimal clinical important, large, and very large effects were conventionally defined [Norman et al., 2003] as half, one, and two SDs, respectively, plus 1° for the measurement error of cephalometric measurements. The standard deviation for an outcome was averaged from the existing trials. Conventional cut-offs of 0.5, 0.8, and 1.3 were adopted for the Standardized Mean Difference (SMD). Conventional cut-offs of 2.0, 4.0, and 8.0 were adopted for the Relative Risk.

Therefore, the following effect magnitudes in the order minimal clinical important effect, large effect, and very large effect were assumed for each outcome:

- SNA angle (average SD of 1.34): MDs of 1.7, 2.4, and 3.7,
- SN-NL & FH-NL angle: SMDs of 0.5, 0.8, 1.3,
- Co-A & Nperp-A: SMDs of 0.5, 0.8, 1.3,
- Nasolabial angle (average SD of 2.99): MDs of 2.5, 4.0, and 7.0,
- Peer Assessment Rating (average SD of 9.88): MDs of 4.9, 9.9, and 19.8.

Finally, the optimal information size (i.e. required meta-analysis sample size) was calculated for each outcome independently in order to detect a minimal clinical difference between two parallel groups with an independent t-test or a chi-square test at $\alpha = 5\%$ and $\beta = 20\%$.

Author contributions

SNP conceived the idea and wrote the first draft of the protocol. SNP, EK, SM, LG, AJ, CB, and TE revised the protocol. SNP performed the literature searches, extracted search hits, and did screening by title. SNP, EK, SM, and LG did study selection by abstract and full-text, did data extraction, and assessed the risk of bias in duplicate, while AJ, CB, and TE resolved any conflicts that arose. SNP handled

communications with trialists, performed the statistical analysis, and wrote the first draft of the manuscript. SNP, EK, SM, LG, AJ, CB, and TE assisted in the interpretation of the results and revised the manuscript draft. SNP submitted the manuscript, is the guarantor and responsible for the accuracy of the data and for future updates of the review.

Post hoc changes to the protocol

- Several subgroup analyses were planned, but could not be performed due to the limited number of trials included in the meta-analyses.

References to Supplementary Data

Higgins JPT, Green S, eds. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available at: www.cochrane-handbook.org. Accessed October 15th 2015.

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Supplementary Table 1. Details of the inclusion/exclusion criteria used in this systematic review. PAR, peer assessment rating; ICON, index of complexity, outcome and need; ABO, American board of orthodontics.

Domain	Inclusion	Exclusion
Participants	Human Class II patients	Animal studies Studies without Class II patients
Interventions	• Any kind of headgear attached intraorally at band or biteplane tubes • Any kind of headgear combined to a fixed orthodontic appliance (but only if the control group received also the same orthodontic appliance without the headgear)	• Combination of headgear and functional appliance • Combination of headgear and mandibular partial appliances (utility arch, lip bumper, etc)
Comparisons	Class II untreated patients	Class I untreated patients
Outcome (primary)	• Skeletal effects of headgear treatment • Effectiveness of headgear to improve malocclusion (PAR, ICON, ABO indeces, etc) • Effect of headgear treatment on quality of life • Adverse effects (effect on upper airways, temporomandibular disorders, root resorption, dental trauma, etc)	• Dental effects of headgear
Study design	• Parallel randomized controlled trials • Parallel prospective non-randomized controlled trials	• Retrospective clinical studies • Case reports/ case series • Non-clinical studies (in vitro, ex vivo, in silico, etc) • Systematic reviews (checked for additional studies)

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Supplementary Table 2. The electronic databases searched, the search strategy used, and the corresponding results (as of December 12th, 2015).

	Search strategy	Limits	
MEDLINE (via PuMed) (http://pubmed.gov/)	((orthodon* AND headgear AND "Class II" AND (control OR untreated OR observ* OR "no treatment"))) NOT retrosp*[Title/Abstract]		120
	orthodon* AND (headgear OR "extraoral traction")	Randomized Controlled trial	81
Web of Knowledge (http://www.webofknowledge.com/)	**TOPIC:** (orthodon* AND headgear AND (control OR untreated) AND "Class II") *NOT* **TOPIC:** (retrosp*)		79
	TOPIC: orthodon* AND (headgear OR "extraoral traction") *AND* **TOPIC:** random*		80
Cochrane Library (http://www.cochranelibrary.com/)	orthodon* AND headgear AND "Class II" AND (control OR untreated OR observ*) in Title, Abstract, Keywords not retrosp* in Title, Abstract, Keywords		48
	orthodon* AND (headgear OR "extraoral traction") AND random*		74
Scopus (http://www.scopus.com/	orthodon* AND headgear AND "Class II" AND (control OR untreated OR observ*) NOT retrosp*		125
	orthodon* AND (headgear OR "extraoral traction") AND random*		131
Virtual Health Library (http://bvsalud.org/ /)	orthodon* AND headgear AND "Class II" AND (control OR untreated OR observ*)		55
	orthodon* AND (headgear OR "extraoral traction") AND random*		7

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Supplementary Table 3. List of studies excluded/included in the systematic review, together with reasons.

Nr	Paper	Decision
	Papers excluded by title	
1	Acar AG, Gursoy S, Dincer M. Molar distalization with a pendulum appliance K-loop combination. Eur J Orthod 2010;32(4):459-65. Epub 2010/03/17.	Excluded by title.
2	Almeida MA, Phillips C, Kula K, Tulloch C. Stability of the palatal rugae as landmarks for analysis of dental casts. The Angle orthodontist. 1995;65(1):43-8. Epub 1995/01/01.	Excluded by title.
3	Almeida RRd. Estudo cefalométrico prospectivo do tratamento da mordida aberta anterior utilizando aparelho removível com grade palatina, associado à mentoneira [Prospective cephalometric study of anterior open bite treatment with removable appliance with palatal crib associated to chincup.168-.	Excluded by title.
4	Armi P, Cozza P, Baccetti T. Effect of RME and headgear treatment on the eruption of palatally displaced canines: a randomized clinical study. The Angle orthodontist. 2011;81(3):370-4. Epub 2011/02/09.	Excluded by title.
5	Baccetti T, Leonardi M, Armi P. A randomized clinical study of two interceptive approaches to palatally displaced canines. Eur J Orthod 2008;30(4):381-5. Epub 2008/06/06.	Excluded by title.
6	Basha AG, Shantaraj R, Mogegowda SB. Comparative Study Between Conventional En-Masse Retraction (Sliding Mechanics) and En-Masse Retraction Using Orthodontic Micro Implant. Implant Dentistry. 2010;19(2):128-36.	Excluded by title.
7	Benson PE, Tinsley D, O'Dwyer JJ, Majumdar A, Doyle P, Sandler PJ. Midpalatal implants vs headgear for orthodontic anchorage - a randomized clinical trial: Cephalometric results. American Journal of Orthodontics and Dentofacial Orthopedics. 2007;132(5):606-15.	Excluded by title.
8	Bogerd CP, Walker I, Bruhwiler PA, Rossi RM. The effect of a helmet on cognitive performance is, at worst, marginal: a controlled laboratory study. Applied ergonomics. 2014;45(3):671-6. Epub 2013/10/26.	Excluded by title.
9	Bondemark L, Karlsson I. Extraoral vs intraoral appliance for distal movement of maxillary first molars: a randomized controlled trial. The Angle orthodontist. 2005;75(5):699-706. Epub 2005/11/11.	Excluded by title.
10	Braham RA, Finch CF, McIntosh A, McCrory P. Community football players' attitudes towards protective equipment--a pre-season measure. British journal of sports medicine. 2004;38(4):426-30. Epub 2004/07/27.	Excluded by title.
11	Braham RA, Finch CF. Do community football players wear allocated protective equipment? Descriptive results from a randomised controlled trial. Journal of science and medicine in sport / Sports Medicine Australia. 2004;7(2):216-20. Epub 2004/09/15.	Excluded by title.
12	Breuning KH, van Strijen PJ, Prahl-Andersen B, Tuinzing DB. Duration of orthodontic treatment and mandibular lengthening by means of distraction or bilateral sagittal split osteotomy in patients with Angle Class II malocclusions. American Journal of Orthodontics and Dentofacial Orthopedics. 2005;127(1):25-9.	Excluded by title.
13	Burhan AS. Combined treatment with headgear and the Frog appliance for maxillary molar distalization: a randomized controlled trial. Korean Journal of Orthodontics. 2013;43(2):101-9.	Excluded by title.
14	Cassis MA. Tratamento da mordida aberta anterior com esporão colado e mentoneira: estudo comparativo dos efeitos dentoalveolares e esqueléticos [Anterior open bite treated with bonded spurs appliance and high-pull chincup therapy: comparative study of dentoalveolar and skeletal effects.205-.	Excluded by title.
15	Chate RAC. Do we really want a quick fix? British Dental Journal. 2000;188(4):177-86.	Excluded by title.
16	Chen M, Li Z-M, Liu X, Cai B, Wang D-W, Feng Z-C. Differences of treatment outcomes between self-ligating brackets with microimplant and headgear anchorages in adults with bimaxillary protrusion. American Journal of Orthodontics and Dentofacial Orthopedics. 2015;147(4):465-71.	Excluded by title.
17	Cozza P, Mucedero M, Baccetti T, Franchi L. Early orthodontic treatment of skeletal open-bite malocclusion: A systematic review. Angle Orthodontist. 2005;75(5):707-13.	Excluded by title.
18	de Almeida MR, Herrero F, Fattal A, Davoody AR, Nanda R, Uribe F. A comparative anchorage control study between conventional and self-ligating bracket systems using differential moments. Angle Orthodontist. 2013;83(6):937-42.	Excluded by title.
19	Feldmann I, Bondemark L. Anchorage capacity of osseointegrated and conventional anchorage systems: a randomized controlled trial.Am J Orthod Dentofac Orthop 2008;133(3):339 e19-28. Epub 2008/03/12.	Excluded by title.
20	Feldmann I, List T, Bondemark L. Orthodontic anchoring techniques and its influence on pain, discomfort, and jaw function-a randomized controlled trial. Eur J Orthod 2012;34(1):102-8.	Excluded by title.
21	Ferreira FPC. Estudo cefalométrico das alterações dentoesqueléticas produzidas pelo aparelho removível com grade palatina, associado à mentoneira, no tratamento da mordida aberta anterior [Cephalometric effects of the dentoskeletal alterations yielded by the removable appliance with tongue crib associated to chincap therapy on the tratment of anterior open bite.155-.	Excluded by title.
22	Freire AB, do Nascimento LEAG, de Lira ALS. Effects induced after the use of maxillary protraction appliances: A literature review. Dental Press Journal of Orthodontics. 2012;17(4):122-8.	Excluded by title.
23	Garfinkle JS, Cunningham LL, Jr., Beeman CS, Kluemper GT, Hicks EP, Kim MO. Evaluation of orthodontic mini-implant anchorage in premolar extraction therapy in adolescents.Am J Orthod Dentofac Orthop 2008;133(5):642-53. Epub 2008/05/06.	Excluded by title.
24	Insoft M, King GJ, Keeling SD. The measurement of acid and alkaline phosphatase in gingival crevicular fluid during orthodontic tooth movement.Am J Orthod Dentofac Orthop 1996;109(3):287-96. Epub 1996/03/01.	Excluded by title.
25	Iwai H, Motoyoshi M, Uchida Y, Matsuoka M, Shimizu N. Effects of tooth root contact on the stability of orthodontic anchor screws in the maxilla: Comparison between self-drilling and self-tapping methods. American Journal of Orthodontics and Dentofacial Orthopedics. 2015;147(4):483-91.	Excluded by title.
26	Jambi S, Thiruvenkatachari B, O'Brien Kevin D, Walsh T. Orthodontic treatment for distalising upper first molars in children and adolescents. Cochrane Database of Systematic Reviews [Internet]. 2013; (10). Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008375.pub2/abstract.	Excluded by title.
27	Jambi S, Walsh T, Sandler J, Benson Philip E, Skeggs Richard M, O'Brien Kevin D. Reinforcement of anchorage	Excluded by title.

	during orthodontic brace treatment with implants or other surgical methods. Cochrane Database of Systematic Reviews [Internet]. 2014; (8). Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005098.pub3/abstract.	
28	Jarvinen S, Widstrom E, Raitio M. Factors affecting the duration of orthodontic treatment in children - A retrospective study. Swedish Dental Journal. 2004;28(2):93-100.	Excluded by title.
29	Jarvinen S, Widstrom E. Determinants of costs of orthodontic treatment in the Finnish public health service. Swedish Dental Journal. 2002;26(1):41-9.	Excluded by title.
30	Jung BA, Wehrbein H, Hopfenmuller W, Harzer W, Gedrange T, Diedrich P, et al. Early loading of plalatal implants (ortho-type II) a prospective multicenter randomized controlled clinical trial. Trials [Internet]. 2007:[24 p.]. Available from: http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/086/CN-00642086/frame.html.	Excluded by title.
31	Kluemper GT, Beeman CS, Hicks EP. Early vs. late orthodontic treatment - Response. Journal of the American Dental Association. 2000;131(10):1410-+.	Excluded by title.
32	Leonardi M, Armi P, Franchi L, Baccetti T. Two interceptive approaches to palatally displaced canines: a prospective longitudinal study. The Angle orthodontist. 2004;74(5):581-6. Epub 2004/11/09.	Excluded by title.
33	Li F, Hu HK, Chen JW, Liu ZP, Li GF, He SS, et al. Comparison of anchorage capacity between implant and headgear during anterior segment retraction A Systematic Review. Angle Orthodontist. 2011;81(5):915-22.	Excluded by title.
34	Ma J, Wang L, Zhang W, Chen W, Zhao C, Smales RJ. Comparative evaluation of micro-implant and headgear anchorage used with a pre-adjusted appliance system. Eur J Orthod 2008;30(3):283-7. Epub 2008/06/10.	Excluded by title.
35	McIntosh AS, McCrory P, Finch CF, Best JP, Chalmers DJ, Wolfe R. Does padded headgear prevent head injury in rugby union football? Medicine and science in sports and exercise. 2009;41(2):306-13. Epub 2009/01/08.	Excluded by title.
36	McIntosh AS, McCrory P, Finch CF, Chalmers DJ, Best JP. Rugby headgear study. Journal of science and medicine in sport / Sports Medicine Australia. 2003;6(3):355-8. Epub 2003/11/12.	Excluded by title.
37	Meikle MC. What do prospective randomized clinical trials tell us about the treatment of Class II malocclusions? A personal viewpoint. Eur J Orthod 2005;27(2):105-14.	Excluded by title.
38	Pandis N, Polychronopoulou A, Eliades T. Active or passive self-ligating brackets? A randomized controlled trial of comparative efficiency in resolving maxillary anterior crowding in adolescents.Am J Orthod Dentofac Orthop 2010;137(1):12 e1-6; discussion -3. Epub 2010/02/04.	Excluded by title.
39	Pietila I, Pietila T, Pirttiniemi P, Varrela J, Alanen P. Orthodontists' views on indications for and timing of orthodontic treatment in Finnish public oral health care. Eur J Orthod 2008;30(1):46-51.	Excluded by title.
40	Polat-Ozsoy O, Gokcelik A, Gungor-Acar A, Kircelli BH. Soft tissue profile after distal molar movement with a pendulum K-loop appliance versus cervical headgear. The Angle orthodontist. 2008;78(2):317-23. Epub 2008/02/07.	Excluded by title.
41	Saleh M, Hajeer MY, Al-Jundi A. Assessment of pain and discomfort during early orthodontic treatment of skeletal Class III malocclusion using the Removable Mandibular Retractor Appliance. European Journal of Paediatric Dentistry. 2013;14(2):119-24.	Excluded by title.
42	Sandler J, Benson PE, Doyle P, Majumder A, O'Dwyer J, Speight P, et al. Palatal implants are a good alternative to headgear: a randomized trial.Am J Orthod Dentofac Orthop 2008;133(1):51-7. Epub 2008/01/05.	Excluded by title.
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47	Thiruvenkatachari B, Al-Abdallah M, Akram NC, Sandler J, O'Brien K. Measuring 3-dimensional tooth movement with a 3-dimensional surface laser scanner. American Journal of Orthodontics and Dentofacial Orthopedics. 2009;135(4):480-5.	Excluded by title.
48	Torres FC. Tratamento da mordida aberta anterior com grade palatina e mentoneira: estudo dos efeitos dentoalveolares e tegumentares [Treatment of anterior open bite with palatal crib and chincup: comparative study of dentoalveolar and soft tissue effects.114-.	Excluded by title.
49	Toy E, Enacar A. The effects of the pendulum distalising appliance and cervical headgear on the dentofacial structures. Australian orthodontic journal. 2011;27(1):10-6. Epub 2011/06/24.	Excluded by title.
50	Trakyali G, Sayinsu K, Muezzinoglu AE, Arun T. Conscious hypnosis as a method for patient motivation in cervical headgear wear--a pilot study. Eur J Orthod 2008;30(2):147-52. Epub 2008/02/12.	Excluded by title.
51	Tulloch JFC, Medland W, Tuncay OC. Methods used to evaluate growth modification in Class II malocclusion. American Journal of Orthodontics and Dentofacial Orthopedics. 1990;98(4):340-7.	Excluded by title.
52	Vause NL, Grantham DW. Effects of earplugs and protective headgear on auditory localization ability in the horizontal plane. Human factors. 1999;41(2):282-94. Epub 1999/07/28.	Excluded by title.
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54	Watkinson S, Harrison Jayne E, Furness S, Worthington Helen V. Orthodontic treatment for prominent lower front	Excluded by title.

	teeth (Class III malocclusion) in children. Cochrane Database of Systematic Reviews [Internet]. 2013; (9). Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003451.pub2/abstract.	
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57	Anne Mandall N, Cousley R, DiBiase A, Dyer F, Littlewood S, Mattick R, et al. Is early Class III protraction facemask treatment effective? A multicentre, randomized, controlled trial: 3-year follow-up. Journal of orthodontics. 2012;39(3):176-85. Epub 2012/09/18.	Excluded by title.
58	Atalay Z, Tortop T. Dentofacial effects of a modified tandem traction bow appliance. Eur J Orthod 2010;32(6):655-61. Epub 2010/03/30.	Excluded by title.
59	Bousquet JA, Jr., Tuesta O, Flores-Mir C. In vivo comparison of force decay between injection molded and die-cut stamped elastomers. Am J Orthod Dentofac Orthop 2006;129(3):384-9. Epub 2006/03/11.	Excluded by title.
60	Ge YS, Liu J, Chen L, Han JL, Guo X. Dentofacial effects of two facemask therapies for maxillary protraction. The Angle orthodontist. 2012;82(6):1083-91. Epub 2012/05/30.	Excluded by title.
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272	McDonagh S, Moss JP, Goodwin P, Lee RT. A prospective optical surface scanning and cephalometric assessment of the effect of functional appliances on the soft tissues. Eur J Orthod 2001;23(2):115-26. Epub 2001/06/12.	Excluded; combination headgear & functional appliance.
273	de Lira AdLSd, Souza MMG, Bolognese AM. Long-term maxillary behavior in treated skeletal Class II malocclusion. Braz j oral sci 2012;11(2):120-4.	Excluded; combination headgear & fixed appliance (brackets); control group did not receive fixed appliance.
274	de Oliveira JN, Jr., Rodrigues de Almeida R, Rodrigues de Almeida M, de Oliveira JN. Dentoskeletal changes induced by the Jasper jumper and cervical headgear appliances followed by fixed orthodontic treatment.Am J Orthod Dentofac Orthop 2007;132(1):54-62.	Excluded; combination headgear & fixed appliance (brackets); control group did not receive fixed appliance.
275	Fischer TJ. The cervical facebow and mandibular rotation. The Angle orthodontist. 1980;50(1):54-62. Epub 1980/01/01.	Excluded; combination headgear & fixed appliance (brackets); control group did not receive fixed appliance.
276	Oliveira Júnior JNd. Avaliação comparativa das alterações dentoesqueléticas promovidas pelos aparelhos Jasper Jumper e extrabucal com ancoragem cervical, ambos associados à aparelhagem fixa no tratamento da classe II, divisão 1, de Angle [Evaluation assessment of dentoskeletal changes produced by the Jasper Jumper appliance and the cervical headgear, both followed by the fixed appliance therapy, for class II, division 1 treatment.235-.	Excluded; combination headgear & fixed appliance (brackets); control group did not receive fixed appliance.
277	de Lira AL, Izquierdo A, Prado S, Issamu Nojima L, Nojima M. Mandibular behavior in the treatment of skeletal Class II malocclusion: A 5-year post-retention analysis. Brazilian Journal of Oral Sciences. 2009;8(4):166-70.	Excluded; no control group.
278	de Lira ALS, Souza MMG, Bolognese AM, Nojima M. Comparison of 2 types of treatment of skeletal Class II malocclusions: A 5-year post-retention analysis. Brazilian Journal of Oral Sciences. 2014;13(4):251-6.	Excluded; no control group.
279	Mergen JL, Southard KA, Dawson DV, Fogle LL, Casko JS, Southard TE. Treatment outcomes of growing Class II Division 1 patients with varying degrees of anteroposterior and vertical dysplasias, Part 2. Profile silhouette evaluation. American Journal of Orthodontics and Dentofacial Orthopedics. 2004;125(4):457-62.	Excluded; no control group.
280	Takahashi S, Ono T, Ishiwata Y, Kuroda T. Effect of wearing cervical headgear on tongue pressure. J Orthod. 2000 Jun;27(2):163-7.	Excluded; no control group.
281	Thurman MM, King GJ, Ramsay DS, Wheeler TT, Phillips C. The effect of an anterior biteplate on dental and skeletal Class II correction using headgears: a cephalometric study. Orthod Craniofac Res 2011;14(4):213-21.	Excluded; no control group.
282	Farret MMB, de Lima EM, Farret MM, de Araújo LL. Dental and skeletal effects of combined headgear used alone or in association with rapid maxillary expansion. Dental Press Journal of Orthodontics. 2015;20(5):43-9.	Excluded; control group not Class II.
283	Ingervall B, Thuer U. Temporal Muscle-Activity during the First Year of Class-Ii, Division-1 Malocclusion Treatment with an Activator. Am J Orthod Dentofac Orthop 1991;99(4):361-8.	Excluded; control group not Class II.
284	Kadkhoda S, Nedjat S, Shirazi M. Comparison of oral-health-related quality of life during treatment with headgear and functional appliances. International journal of paediatric dentistry / the British Paedodontic Society [and] the International Association of Dentistry for Children. 2011;21(5):369-73. Epub 2011/06/01.	Excluded; control group not Class II.
285	Marchiori Farret M, de Lima EM, Pereira Araujo V, Deon Rizzatto SM, Macedo de Menezes L, Lima Grossi M. Molar changes with cervical headgear alone or in combination with rapid maxillary expansion. The Angle orthodontist. 2008;78(5):847-51. Epub 2008/02/27.	Excluded; control group not Class II.
286	Varlik SK, Iscan HN. The effects of cervical headgear with an expanded inner bow in the permanent dentition. Eur J Orthod 2008;30(4):425-30. Epub 2008/08/06.	Excluded; control group not Class II.
287	Araújo MA. Efeitos dentários dos aparelhos extrabucais removíveis no tratamento da Classe II [Dental effects of removable extraoral appliances on Class II treatment. Dissertation 2010; 89-.	Excluded; pure dental effects of headgear.
288	Ashmore JL, Kurland BF, King GJ, Wheeler TT, Ghafari J, Ramsay DS. A 3-dimensional analysis of molar movement during headgear treatment. American Journal of Orthodontics and Dentofacial Orthopedics. 2002;121(1):18-29.	Excluded; pure dental effects of headgear.
289	Henriques FP, Janson G, Henriques JFC, Pupulim DC. Effects of cervical headgear appliance: a systematic review. Dental Press J Orthod. 2015 July-Aug;20(4):76-81.	Excluded; pure dental effects of headgear.
290	Silvola AS, Arvonen P, Julku J, Lahdesmaki R, Kantomaa T, Pirttiniemi P. Early headgear effects on the eruption pattern of the maxillary canines. The Angle orthodontist. 2009;79(3):540-5. Epub 2009/05/06.	Excluded; pure dental effects of headgear.
291	Antonarakis GS, Killiaridis S. Short-term anteroposterior treatment effects of functional appliances and extraoral traction on Class II malocclusion - A meta-analysis. Angle Orthodontist. 2007;77(5):907-14.	Excluded; systematic review (reference/citation lists checked).
292	Bondemark L, Holm A-K, Hansen K, Axelsson S, Mohlin B, Brattstrom V, et al. Long-term stability of orthodontic treatment and patient satisfaction - A systematic review. Angle Orthodontist. 2007;77(1):181-91.	Excluded; systematic review (reference/citation lists checked).
293	D'Anto V, Bucci R, Franchi L, Rongo R, Michelotti A, Martina R. Class II functional orthopaedic treatment: a systematic review of systematic reviews. Journal of Oral Rehabilitation. 2015;42(8):624-42.	Excluded; systematic review (reference/citation lists checked).
294	Jacob HB, Buschang PH, Santos-Pinto Ad. Class II malocclusion treatment using high-pull headgear with a splint: a systematic review. Dental Press Journal of Orthodontics. 2013;18(2):21e1-e7.	Excluded; systematic review (reference/citation lists checked).

295	Jacobs T, Sawaengkit P. National Institute of Dental and Craniofacial Research Efficacy Trials of Bionator Class II Treatment: A Review. Angle Orthodontist. 2002;72(6):571-5.	Excluded; systematic review (reference/citation lists checked).
296	Millett Declan T, Cunningham S, O'Brien Kevin D, Benson Philip E, Williams A, de Oliveira Cesar M. Orthodontic treatment for deep bite and retroclined upper front teeth in children. Cochrane Database of Systematic Reviews [Internet]. 2006; (4). Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005972.pub2/abstract.	Excluded; systematic review (reference/citation lists checked).
297	Sunnak R, Johal A, Fleming PS. Is orthodontics prior to 11 years of age evidence-based? A systematic review and meta-analysis. Journal of Dentistry. 2015;43(5):477-86.	Excluded; systematic review (reference/citation lists checked).
298	Thiruvenkatachari B, Harrison J, Worthington H, O'Brien K. Early orthodontic treatment for Class II malocclusion reduces the chance of incisal trauma: Results of a Cochrane systematic review. American Journal of Orthodontics and Dentofacial Orthopedics. 2015;148(1):47-59.	Excluded; systematic review (reference/citation lists checked).
299	Thiruvenkatachari B, Harrison Jayne E, Worthington Helen V, O'Brien Kevin D. Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children. Cochrane Database of Systematic Reviews [Internet]. 2013; (11).	Excluded; systematic review (reference/citation lists checked).
	Included papers	
300	Abed Y, Brin I. Early headgear effect on the eruption pattern of maxillary second molars. Angle Orthod. 2010 Jul;80(4):454-60.	Included
301	Altug Z, Yeşilbag GP. [New and different approach for Class II division 1 malocclusions: Altuğ type maxillar expander and distalization appliance part 1 sagittal dimension evaluation]. Turk J Orthod 2004;17(3):245-263.	Included
302	Altug Z, Yeşilbag GP. [New and different approach for Class II division 1 malocclusions: Altuğ type maxillar expander and distalization appliance part 2 transversal dimension evaluation]. Turk J Orthod 2004;17(3):264-278.	Included
303	Brazeau L. Cephalometric analysis of posttreatment changes in Class II division 1 patients treated in either one or two phases. University of Florida, 2004, Dissertation.	Included
304	Brin I, Tulloch JFC, Koroluk L, Philips C. External apical root resorption in Class II malocclusion: A retrospective review of 1-versus 2-phase treatment. American Journal of Orthodontics and Dentofacial Orthopedics. 2003;124(2):151-6.	Included
305	Chen DR, McGorray SP, Dolce C, Wheeler TT. Effect of early Class II treatment on the incidence of incisor trauma. Am J Orthod Dentofac Orthop 2011;140(4):e155-60.	Included
306	Dolce C, Babh LK, McGorray SP, Taylor MG, King GJ, Wheeler TT. Vertical skeletal and dental changes in early treatment of class II malocclusion. Sem Orthod 2002;8(3):141-8.	Included
307	Dolce C, McGorray SP, Brazeau L, King GJ, Wheeler TT. Timing of Class II treatment: skeletal changes comparing 1-phase and 2-phase treatment.Am J Orthod Dentofac Orthop 2007;132(4):481-9.	Included
308	Dolce C, Schader RE, McGorray SP, Wheeler TT. Centrographic analysis of 1-phase versus 2-phase treatment for Class II malocclusion.Am J Orthod Dentofac Orthop 2005;128(2):195-200.	Included
309	Fernandes ÁF, Brunharo IH, Quintão CC, Costa MG, de Oliveira-Costa MR. Effectiveness of twin blocks and extraoral maxillary splint (Thurow) appliances for the correction of Class II relationships. World J Orthod. 2010 Fall;11(3):230-5.	Included
310	Fernandes AFC. [Comparative study of two therapies for Class II skeletal malocclusion treatment: Twin Block functional appliance and extra-oral maxillary splint]. Universidade do Estado do Rio de Janeiro (UERJ), Rio de Janeiro, 2007, Dissertation.	Included
311	Firatli S, Ülgen M. [The effects of cervical headgear on the cervical vertebrae]. Turk J Orthod 1995;8(2):214-222.	Included
312	Firouz M, Zernik J, Nanda R. Dental and orthopedic effects of high-pull headgear in treatment of Class II, division 1 malocclusion. Am J Orthod Dentofac Orthop 1992;102(3):197-205.	Included
313	Fry JR. A Comparison of the Soft Tissue Outcomes of One and Two Phase Class II Orthodontic Treatment. University of Southern California, 2006, Dissertation.	Included
314	Gültan A. [The effect of cervical headgear on the cant of occlusal plane]. Turk Ortodonti Derg 1989;2(2):209-14.	Included
315	Henriques RP, Henriques JFC, Almeida RRd, Freitas MRd, Janson G. Estudo das alterações decorrentes do uso do aparelho extrabucal de tração occipital na correção da má oclusão de Classe II, 1ª divisão [Study of alterations in the Class II division 1 malocclusion in young individuals treated with occipital headgear (IHG). Rev dent press ortodon ortopedi facial 2007;12(4):72-83.	Included
316	Henriques RP. Estudo cefalométrico comparativo das alterações decorrentes do uso de dois tipos de aparelhos extrabucais em jovens com má oclusão de Classe II: 1º divisão de Angle [Comparative cephalometric study of alterations in the Angle Class II division 1 malocclusion in young individuals treated with two types of headgear]. Universidade de São Paulo, 2004; Dissertation.	Included
317	Jakobsson SO. Cephalometric evaluation of treatment effect on Class II, Division 1 malocclusions. Am J Orthod 1967;53(6):446-57.	Included
318	Keeling SD, Garvan CW, King GJ, Wheeler TT, McGorray S. Temporomandibular disorders after early Class II treatment with bionators and headgears: results from a randomized controlled trial. Sem Orthod 1995;1(3):149-64.	Included
319	Keeling SD, Wheeler TT, King GJ, Garvan CW, Cohen DA, Cabassa S, et al. Anteroposterior skeletal and dental changes after early Class II treatment with bionators and headgear.Am J Orthod Dentofac Orthop 1998;113(1):40-50.	Included
320	King GJ, McGorray SP, Wheeler TT, Dolce C, Taylor M. Comparison of peer assessment ratings (PAR) from 1-phase and 2-phase treatment protocols for Class II malocclusions. Am J Orthod Dentofac Orthop 2003;123(5):489-96.	Included
321	King GJ, Wheeler TT, McGorray SP, Aiosa LS, Bloom RM, Taylor MG. Orthodontists' perceptions of the impact of phase 1 treatment for Class II malocclusion on phase 2 needs. J Dent Res 1999;78(11):1745-53.	Included
322	Kocadereli IL, Ciger S. [The cephalometric evaluation of dental and soft tissue effects of Frankel 2 (FR2) and headgear appliances on Class II, division 1 malocclusion]. Turk J Orthod 1992;5(2):98-110.	Included

323	Kocadereli IL, Ciger S. The skeletal effects of Frankel 2 (FR2) and headgear appliances on Class II, division 1 malocclusion. Turk J Orthod 1993;6(2):145-152.	Included
324	Koroluk LD, Tulloch JF, Phillips C. Incisor trauma and early treatment for Class II Division 1 malocclusion.Am J Orthod Dentofac Orthop 2003;123(2):117-25.	Included
325	Krusinskiene V, Kiuttu P, Julku J, Silvola A-S, Kantomaa T, Pirttiniemi P. A randomized controlled study of early headgear treatment on occlusal stability - a 13 year follow-up. Eur J Orthod 2008;30(4):418-24.	Included
326	Krusinskiene V. The effect of early headgear treatment on the dental arches. Kaunas University of Medicine, 2010, Dissertation.	Included
327	Kumar S, Pentapati KC. Effect of low pull headgear on head position. Saudi Dent J. 2013 Jan;25(1):23-7.	Included
328	Mantysaari R, Kantomaa T, Pirttiniemi P, Pykalainen A. The effects of early headgear treatment on dental arches and craniofacial morphology: a report of a 2 year randomized study. Eur J Orthod 2004;26(1):59-64.	Included
329	Nahas ACR. Cephalometric study in patients that displayed Class II, division 1 malocclusion treated with Herbst and high-pull headgear appliances. University of Sao Paulo, 2003, Dissertation.	Included
330	Nahás-Scocate ACR, Henriques JFC, Tompson BD, Woodside DG, Martins PO. Efeitos dentoesqueléticos do aparelho extrabucal de tração occipital no tratamento da má-oclusão de classe II, divisão 1 [Dentoskeletal effects of the extraoral occipital traction appliance on the treatment of class II, division 1 malocclusion. Ortodontia.41(n.esp):263-71.	Included
331	Ölmez H, Sagdic D, Erdogan E. The effect of the combination of maxillary splint and high-pull headgear on dentofacial system. Turk J Orthod 1994;7(2):127-133.	Included
332	Paulin RF. Natural rotational pattern of the dentofacial structures and induced by the treatment with the modified Thurow appliance extra oral: Cephalometric study with metallic implants. Universidade Estadual Paulista “Júlio de Mesquita Filho”, 2004; Dissertation.	Included
333	Pavlow SS, McGorray SP, Taylor MG, Dolce C, King GJ, Wheeler TT. Effect of early treatment on stability of occlusion in patients with Class II malocclusion.Am J Orthod Dentofac Orthop 2008;133(2):235-44.	Included
334	Pires AM, Oliveira AG, Oliveira Jr. G, Oliveira Jr. JN. Comparative cephalometric study of the vertical alterations occurred in patients treated with maxillary orthopedic splint, considering two different force application points: anterior and posterior. J Bras Ortodon Ortop Facial 2003;8(45):208-222.	Included
335	Pirttiniemi P, Kantomaa T, Mantysaari R, Pykalainen A, Krusinskiene V, Laitala T, et al. The effects of early headgear treatment on dental arches and craniofacial morphology: an 8 year report of a randomized study. Eur J Orthod 2005;27(5):429-36.	Included
336	Ritter DE, Almeida MAdO. Tratamento precoce da maloclusão de Classe II, divisão 1, com splint de tração maxilar - estudo clínico prospectivo [Early treatment of Class II division 1 malocclusion with maxillary traction splint - prospective clinical trial. Ortodon gaúch 2002;6(2):154-66.	Included
337	Santos-Pinto A, Paulin RF, Pinto PRS, Gandini Júnior LG, Martins LP, Raveli DB. Tratamento da classe II hiperdivergente com o aparelho extra bucal de Thurow modificado. Revista da Sociedade Brasileira de Ortodontia 2010;6(1):1-9.	Included
338	Tosun Y, Isiksal E. [The effects of high pull headgear on denfofacial complex in Class II division 1 cases]. Turk J Orthod 1991;4(1):50-54.	Included
339	Tulloch JF, Phillips C, Koch G, Proffit WR. The effect of early intervention on skeletal pattern in Class II malocclusion: a randomized clinical trial.Am J Orthod Dentofac Orthop 1997;111(4):391-400.	Included
340	Tulloch JF, Phillips C, Proffit WR. Benefit of early Class II treatment: progress report of a two-phase randomized clinical trial.Am J Orthod Dentofac Orthop 1998;113(1):62-72.	Included
341	Tulloch JF, Proffit WR, Phillips C. Influences on the outcome of early treatment for Class II malocclusion.Am J Orthod Dentofac Orthop 1997;111(5):533-42.	Included
342	Tulloch JF, Proffit WR, Phillips C. Outcomes in a 2-phase randomized clinical trial of early Class II treatment.Am J Orthod Dentofac Orthop 2004;125(6):657-67.	Included
343	Ülgen M, Işcan HN, Gögen H. [Changes occured in the mandibular morphology during the treatment of Class II division 1 cases with cervical headgear]. Turk J Orthod 1991;3(2):71-78.	Included
344	Virkkula T, Kantomaa T, Julku J, Pirttiniemi P. Long-term soft-tissue response to orthodontic treatment with early cervical headgear-a randomized study. Am J Orthod Dentofac Orthop 2009;135(5):586-96.	Included
345	Wheeler TT, McGorray SP, Dolce C, Taylor MG, King GJ. Effectiveness of early treatment of Class II malocclusion.Am J Orthod Dentofac Orthop 2002;121(1):9-17.	Included
346	Wortham JR, Dolce C, McGorray SP, Le H, King GJ, Wheeler TT. Comparison of arch dimension changes in 1-phase vs 2-phase treatment of Class II malocclusion.Am J Orthod Dentofac Orthop 2009;136(1):65-74.	Included
347	Zhang L, Luo Y, Wang RF. [The effect of cervical headgear and lower utility arch on the control of vertical dimension in tooth and jaw]. Shanghai kou qiang yi xue = Shanghai journal of stomatology. 2010;19(4):383-6.	Included

Collation of multiple reports from the same trial – List of unique included trials

No.	Paper	Trial
1	Altug Z, Yeşilbag GP. [New and different approach for Class II division 1 malocclusions: Altuğ type maxillar expander and distalization appliance part 1 sagittal dimension evaluation]. Turk J Orthod 2004;17(3):245-263.	Altug 2004 collated
2	Altug Z, Yeşilbag GP. [New and different approach for Class II division 1 malocclusions: Altuğ type maxillar expander and distalization appliance part 2 transversal dimension evaluation]. Turk J Orthod 2004;17(3):264-278.	
3	Fernandes AFC. [Comparative study of two therapies for Class II skeletal malocclusion treatment: Twin Block functional appliance and extra-oral maxillary splint]. Universidade do Estado do Rio de Janeiro (UERJ), Rio de Janeiro, 2007, Dissertation.	Fernandes 2007 collated
4	Fernandes ÂF, Brunharo IH, Quintão CC, Costa MG, de Oliveira-Costa MR. Effectiveness of twin blocks and	

	extraoral maxillary splint (Thurow) appliances for the correction of Class II relationships. World J Orthod. 2010 Fall;11(3):230-5.	
5	Firouz M, Zernik J, Nanda R. Dental and orthopedic effects of high-pull headgear in treatment of Class II, division 1 malocclusion. Am J Orthod Dentofac Orthop 1992;102(3):197-205.	Firouz 1992
6	Henriques RP. Comparative cephalometric study of alterations in the Angle Class II division 1 malocclusion in young individuals treated with two types of headgear. Universidade de São Paulo, 2004; Dissertation.	Henriques 2004 collated
7	Henriques RP, Henriques JFC, Almeida RRd, Freitas MRd, Janson G. Estudo das alterações decorrentes do uso do aparelho extrabucal de tração occipital na correção da má oclusão de Classe II, 1ª divisão [Study of alterations in the Class II division 1 malocclusion in young individuals treated with occipital headgear (IHG). Rev dent press ortodon ortopedi facial 2007;12(4):72-83.	
8	Jakobsson SO. Cephalometric evaluation of treatment effect on Class II, Division 1 malocclusions. Am J Orthod 1967;53(6):446-57.	Jakobsson 1967
9	Brazeau L. Cephalometric analysis of posttreatment changes in Class II division 1 patients treated in either one or two phases. University of Florida, 2004, Dissertation.	Keeling 1995 collated
10	Chen DR, McGorray SP, Dolce C, Wheeler TT. Effect of early Class II treatment on the incidence of incisor trauma. Am J Orthod Dentofac Orthop 2011;140(4):e155-60.	
11	Dolce C, Babh LK, McGorray SP, Taylor MG, King GJ, Wheeler TT. Vertical skeletal and dental changes in early treatment of class II malocclusion. Sem Orthod 2002;8(3):141-8.	
12	Dolce C, McGorray SP, Brazeau L, King GJ, Wheeler TT. Timing of Class II treatment: skeletal changes comparing 1-phase and 2-phase treatment.Am J Orthod Dentofac Orthop 2007;132(4):481-9.	
13	Dolce C, Schader RE, McGorray SP, Wheeler TT. Centrographic analysis of 1-phase versus 2-phase treatment for Class II malocclusion.Am J Orthod Dentofac Orthop 2005;128(2):195-200.	
14	Keeling SD, Garvan CW, King GJ, Wheeler TT, McGorray S. Temporomandibular disorders after early Class II treatment with bionators and headgears: results from a randomized controlled trial. Sem Orthod 1995;1(3):149-64.	
15	Keeling SD, Wheeler TT, King GJ, Garvan CW, Cohen DA, Cabassa S, et al. Anteroposterior skeletal and dental changes after early Class II treatment with bionators and headgear.Am J Orthod Dentofac Orthop 1998;113(1):40-50.	
16	King GJ, McGorray SP, Wheeler TT, Dolce C, Taylor M. Comparison of peer assessment ratings (PAR) from 1-phase and 2-phase treatment protocols for Class II malocclusions. Am J Orthod Dentofac Orthop 2003;123(5):489-96.	
17	King GJ, Wheeler TT, McGorray SP, Aiosa LS, Bloom RM, Taylor MG. Orthodontists' perceptions of the impact of phase 1 treatment for Class II malocclusion on phase 2 needs. J Dent Res 1999;78(11):1745-53.	
18	Pavlow SS, McGorray SP, Taylor MG, Dolce C, King GJ, Wheeler TT. Effect of early treatment on stability of occlusion in patients with Class II malocclusion.Am J Orthod Dentofac Orthop 2008;133(2):235-44.	
19	Wheeler TT, McGorray SP, Dolce C, Taylor MG, King GJ. Effectiveness of early treatment of Class II malocclusion.Am J Orthod Dentofac Orthop 2002;121(1):9-17.	
20	Wortham JR, Dolce C, McGorray SP, Le H, King GJ, Wheeler TT. Comparison of arch dimension changes in 1-phase vs 2-phase treatment of Class II malocclusion.Am J Orthod Dentofac Orthop 2009;136(1):65-74.	
21	Kocadereli IL, Ciger S. [The cephalometric evaluation of dental and soft tissue effects of Frankel 2 (FR2) and headgear appliances on Class II, division 1 malocclusion]. Turk J Orthod 1992;5(2):98-110.	Kocadereli 1992 collated
22	Kocadereli IL, Ciger S. The skeletal effects of Frankel 2 (FR2) and headgear appliances on Class II, division 1 malocclusion. Turk J Orthod 1993;6(2):145-152.	
23	Kumar S, Pentapati KC. Effect of low pull headgear on head position. Saudi Dent J. 2013 Jan;25(1):23-7.	Kumar 2013
24	Krusinskiene V, Kiuttu P, Julku J, Silvola A-S, Kantomaa T, Pirttiniemi P. A randomized controlled study of early headgear treatment on occlusal stability - a 13 year follow-up. Eur J Orthod 2008;30(4):418-24.	Mäntysaari 2004 collated
25	Mäntysaari R, Kantomaa T, Pirttiniemi P, Pykalainen A. The effects of early headgear treatment on dental arches and craniofacial morphology: a report of a 2 year randomized study. Eur J Orthod 2004;26(1):59-64.	
26	Pirttiniemi P, Kantomaa T, Mantysaari R, Pykalainen A, Krusinskiene V, Laitala T, et al. The effects of early headgear treatment on dental arches and craniofacial morphology: an 8 year report of a randomized study. Eur J Orthod 2005;27(5):429-36.	
27	Virkkula T, Kantomaa T, Julku J, Pirttiniemi P. Long-term soft-tissue response to orthodontic treatment with early cervical headgear-a randomized study. Am J Orthod Dentofac Orthop 2009;135(5):586-96.	
28	Krusinskiene V. The effect of early headgear treatment on the dental arches. Kaunas University of Medicine, 2010, Dissertation.	
29	Nahas ACR. Cephalometric study in patients that displayed Class II, division 1 malocclusion treated with Herbst and high-pull headgear appliances. University of Sao Paulo, 2003, Dissertation.	Nahas 2003 collated
30	Nahás-Scocate ACR, Henriques JFC, Tompson BD, Woodside DG, Martins PO. Efeitos dentoesqueléticos do aparelho extrabucal de tração occipital no tratamento da má-oclusão de classe II, divisão 1 [Dentoskeletal effects of the extraoral occipital traction appliance on the treatment of class II, division 1 malocclusion. Ortodontia.41(n.esp):263-71.	
31	Ölmez H, Sagdic D, Erdogan E. The effect of the combination of maxillary splint and high-pull headgear on dentofacial system. Turk J Orthod 1994;7(2):127-133.	Ölmez 1994
32	Paulin RF. Natural rotational pattern of the dentofacial structures and induced by the treatment with the modified Thurow appliance extra oral: Cephalometric study with metallic implants. Universidade Estadual Paulista “Júlio de Mesquita Filho”, 2004; Dissertation.	Paulin 2004 collated
33	Santos-Pinto A, Paulin RF, Pinto PRS, Gandini Júnior LG, Martins LP, Raveli DB. Tratamento da classe II hiperdivergente com o aparelho extra bucal de Thurow modificado. Revista da Sociedade Brasileira de Ortodontia	

	2010;6(1):1-9.	
34	Pires AM, Oliveira AG, Oliveira Jr. G, Oliveira Jr. JN. Comparative cephalometric study of the vertical alterations occurred in patients treated with maxillary orthopedic splint, considering two different force application points: anterior and posterior. J Bras Ortodon Ortop Facial 2003;8(45):208-222.	Pires 2003
35	Ritter DE, Almeida MAdO. Tratamento precoce da maloclusão de Classe II, divisão 1, com splint de tração maxilar - estudo clínico prospectivo [Early treatment of Class II division 1 malocclusion with maxillary traction splint - prospective clinical trial. Ortodon gaúch 2002;6(2):154-66.	Ritter 2002
36	Tosun Y, Isiksal E. [The effects of high pull headgear on denfofacial complex in Class II division 1 cases]. Turk J Orthod 1991;4(1):50-54.	Tosun 1991
37	Fry JR. A Comparison of the Soft Tissue Outcomes of One and Two Phase Class II Orthodontic Treatment. University of Southern California, 2006, Dissertation.	Tulloch 1997 collated
38	Koroluk LD, Tulloch JF, Phillips C. Incisor trauma and early treatment for Class II Division 1 malocclusion.Am J Orthod Dentofac Orthop 2003;123(2):117-25.	
39	Tulloch JF, Phillips C, Koch G, Proffit WR. The effect of early intervention on skeletal pattern in Class II malocclusion: a randomized clinical trial.Am J Orthod Dentofac Orthop 1997;111(4):391-400.	
40	Tulloch JF, Phillips C, Proffit WR. Benefit of early Class II treatment: progress report of a two-phase randomized clinical trial.Am J Orthod Dentofac Orthop 1998;113(1):62-72.	
41	Tulloch JF, Proffit WR, Phillips C. Influences on the outcome of early treatment for Class II malocclusion.Am J Orthod Dentofac Orthop 1997;111(5):533-42.	
42	Tulloch JF, Proffit WR, Phillips C. Outcomes in a 2-phase randomized clinical trial of early Class II treatment.Am J Orthod Dentofac Orthop 2004;125(6):657-67.	
43	Brin I, Tulloch JFC, Koroluk L, Philips C. External apical root resorption in Class II malocclusion: A retrospective review of 1-versus 2-phase treatment. American Journal of Orthodontics and Dentofacial Orthopedics. 2003;124(2):151-6.	
44	Abed Y, Brin I. Early headgear effect on the eruption pattern of maxillary second molars. Angle Orthod. 2010 Jul;80(4):454-60.	
45	Firatli S, Ülgen M. [The effects of cervical headgear on the cervical vertebrae]. Turk J Orthod 1995;8(2):214-222.	Ülgen 1991 collated
46	Ülgen M, Işcan HN, Gögen H. [Changes occured in the mandibular morphology during the treatment of Class II division 1 cases with cervical headgear]. Turk J Orthod 1991;3(2):71-78.	
47	Zhang L, Luo Y, Wang RF. [The effect of cervical headgear and lower utility arch on the control of vertical dimension in tooth and jaw]. Shanghai kou qiang yi xue = Shanghai journal of stomatology. 2010;19(4):383-6.	Zhang 2010

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Supplementary Table 4. Details about the risk of bias assessment of included randomized trials with the Cochrane tool. HG, headgear; Ctr, control; PAR, peer assessment rating; SD, standard deviation; ITT, intent to treat.

Trial	Sequence generation	Allocation concealment	Blinding of participants, personnel	Blinding of outcome assessors	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Fernandes 2007	Unclear - randomization description inadequate: "(Cinqüenta e oito pacientes foram selecionados e distribuídos aleatoriamente nos três grupos de acompanhamento da pesquisa.)"	Unclear - no mention throughout the paper.	Unclear - no mention of blinding throughout the paper; blinding is impractical for both patient and clinician.	High risk - no mention of blinding throughout the paper; blinding could have been implemented.	Low risk - No drop-outs or patient losses are reported.	Unclear - It is difficult to judge whether selective reporting is a problem, as no protocol exists.	Unclear - residual bias cannot be excluded.
Keeling 1995	High risk - sequence generation adequate, but problematic: "A stratified block-randomization procedure was used to assign each subject to a treatment protocol. Each subject had an equal likelihood of assignment to an observation, retention, or no-retention group. In addition, subjects assigned to undergo retention or no retention were equally likely to be assigned to undergo treatment with headgear/maxillary retainer with bite plane or treatment with a bionator. We used several criteria to define strata:...". However, according to a previous review, including communication with the trialists (PMID: 24226169): "Subjects initially were selected in blocks of six and randomized to the treatment protocols. This procedure of assigning subjects to groups only after a block had filled was modified in year 3, after we recognised slow entry rate and many partially filled blocks (23% of the sample) were randomized to groups"	Unclear - no mention throughout the paper.	Low risk - no mention of blinding throughout the paper; blinding is impractical for both patient and clinician. However after headgear application, patients were rotated among unaware clinicians every month who checked all interventions: "To control for proficiency bias, each child's clinic appointments were rotated among the four project orthodontists. Children wearing appliances were scheduled for a visit once each month; children without appliances were scheduled for a visit once every 3 months". This (together with the care taken throughout the planning and conduct	Low risk - blinding of outcomes performed: "All appliances were removed by the clinic dental assistant (a dentist) at each data-collection appointment before the examiner obtained any data, including radiographs, and replaced, as necessary, afterward, so that examiners would remain blinded to treatment group and treatment stage....The investigator (S.S.P.) who scored the PAR indexes was calibrated and blinded to the phase-1 treatment group.". Also information from a previous review, including communication with the trialists (PMID: 24226169): "All cephalometric radiographs were encoded by the staff assistant and then decoded for analysis".	Low risk - "Initial data from trial participants and dropouts were compared in these categories to determine whether the subjects lost to follow-up significantly biased the initial randomization. With the exception of race, there were no significant differences between the dropouts and the subjects....An intent-to-treat analysis was also performed, comparing the last PAR score for all subjects who entered the study. Mean PAR scores for this variable were 8.87 (SD 7.26), 8.49 (SD 8.61), and 8.42 (SD 7.65) for bionator, headgear, and observation groups, respectively (P .89).": Drop-out was 24.6%, slightly above the usual cut-off of 20%. However, as drop-outs were balanced among groups, the analysis of drop-outs did not indicate any factors other than race, and the total drop-outs were spread in the initial trial, its retention, and its subsequent extension (around 7%, 11%, and 9%, respectively), we judged that the large drop-out rate was more due to the trial design and patient	Low risk - It is difficult to judge whether selective reporting is a problem, as no protocol exists. However, there multiple reports have been identified with a large variety of outcomes, and protocol violations have been listed in the trial's published report; judged to be in low risk.	Low risk - some factor have not been taken into account in the appliances (like type of Class II malocclusion and patient compliance), but as the study was randomized with adequate sample, the effect of these can be expected to be the same across groups.

			of the trial) were used to judge this field to be in low risk of bias.		specifities, but not associated to treatment allocation; therefore no increased risk of bias exists.		
Mäntysaari 2004	Low risk - generation of the randomized sequence somewhat unclear, but given the overall state of the available report, probably adequate: "The children were randomly divided into two groups of equal size, matched according to gender. This was undertaken by one author (TK) using random numbers".	Low risk - allocation concealment somewhat unclear, but it seems to be probably adequate (central allocation): "To conceal the allocation, most of the practitioners who undertook the treatment were not given information concerning the aim or rationale of the study".	Unclear - no mention of blinding throughout the paper; blinding is impractical for both patient and clinician.	High risk - no mention of blinding throughout the paper; blinding could have been implemented.	Low risk - patient losses due to treatment discontinuation are relatively similar (3 and 2 patients in the HG and Ctr groups, respectively).	Unclear - It is difficult to judge whether selective reporting is a problem, as no protocol exists.	Unclear - residual bias cannot be excluded.
Ritter 2002	Unclear - randomization description inadequate: "(Foram reunidas 20 criancas que cumpriam esses pre-requisitos, totalizando a amostra, a qual foi dividida aleatoriamente dois grupos chamados de grupos Controle e Ativo.)"	Unclear - no mention throughout the paper.	Unclear - no mention of blinding throughout the paper; blinding is impractical for both patient and clinician.	High risk - no mention of blinding throughout the paper; blinding could have been implemented.	Low risk - No drop-outs or patient losses are reported.	Unclear - It is difficult to judge whether selective reporting is a problem, as no protocol exists.	Unclear - residual bias cannot be excluded.
Tulloch 1997	Low risk - sequence generation adequate: "In phase 1 of the trial, each child was randomly assigned by using a stratified block randomization, with gender as the stratification factor, to one of three groups, headgear, functional appliance, or observation only. Randomization was performed within gender in blocks of six patients with Proc	Low risk - allocation sequence fully concealed: "The randomization sequence was prepared by the study biostatistician and given to the study	Low risk - blinding is impractical for both patient and clinician; however, authors went to great extent to blind the outcome assessment, which was objective in nature.	Low risk - blinding of outcome assessors attempted at first phase, although only partially successful: "At the examination, the examiners were blind to the patient's initial group assignment. However, because the molar bands of the headgear patients were not always removed after the first stage of treatment, this blinding was only partial". Blinding attemped and	Low risk - relatively low drop out rate; missing patients were appropriately imputed: "Because 11 of the ITT sample only had initial records, their 15-month measures were imputed with regression coefficients from least squares regression analyses that included baseline measures, treatment group, and gender as explanatory factors."	Low risk - It is difficult to judge whether selective reporting is a problem, as no protocol exists. However, there multiple reports have been identified with a	Low risk - some factor have not been taken into account in the appliances (like type of Class II malocclusion and patient compliance), but as the study was randomized with

	Plan in SAS. 1"	coordinator, who was responsible for assigning subjects to the next clinician on the list. The allocation sequence was concealed from the clinicians".		completely successful at the final report: "Each cephalogram was traced and digitized, by using the UNC 140-point model, by 1 of 2 experienced research technicians, who were masked to the early treatment group when analyzing the final cephalogram."		large variety of outcomes, and protocol violations have been listed in the trial's published report; judged to be in low risk.	adequate sample, the effect of these can be expected to be the same across groups.

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Supplementary Table 5. Details for the risk of bias assessment of non-randomized trials according to the ACROBAT-NRSI (A Cochrane Risk Of Bias Assessment Tool: for Non-Randomized Studies of Interventions). The full completed forms for each separate trials can be requested from the corresponding author. NI, no information.

Domain / **Study**	**Altug 2004**	**Firouz 1992**	**Henriques 2004**	**Jakobsson 1967**	**Kocadereli 1992**	**Kumar 2013**	**Nahas 2003**	**Ölmez 1994**	**Paulin 2004**	**Pires 2003**	**Tosun 1991**	**Ulgen 1991**	**Zhang 2010**
1. Bias due to confounding	Moderate	Serious	Serious	Moderate	Serious	Low	Serious	Moderate	Serious	Critical	Serious	Moderate	Moderate
2. Bias in selection of participants into the study	NI	NI	NI	Low	NI	NI	Serious	NI	Serious	NI	Serious	NI	NI
3. Bias in measurement of interventions	NI	Low	Low	Low	Low	NI	Low	Low	Low	Low	Low	NI	Low
4. Bias due to departures from intended interventions	NI	Low	NI	NI	NI	Low	Low	NI	NI	NI	Low	NI	NI
5. Bias due to missing data	Low	Low	Low	Moderate	Low	Low	Low	Low	Low	Low	Low	Low	Low
6. Bias in measurement of outcomes	Serious	Serious	Serious	Serious	Serious	Serious	Serious	Serious	Serious	Serious	Serious	Serious	Serious
7. Bias in selection of the reported result	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Overall	Serious	Serious	Serious	Serious	Serious	Serious	Serious	Serious	Serious	Critical	Serious	Serious	Serious

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Supplementary Table 6. Additional outcomes reported from the included studies. CI, confidence interval; HG, headgear; Ctr, control; Ph1, phase 1 (headgear treatment/observation); yr, year; RR, relative risk; Tx, treatment; Ph2, phase 2 (fixed appliance treatment after headgear/ observation); MD, mean difference; PAR, peer assessment rating; EARR, external apical root resorption; Ret, retention; TMJ, temporomandibular joint.

	Outcome	n	Time	Metric	Effect (95% CI)	P	I^2	What happens to HG pts compared to Ctr pts
Effectiveness / efficiency								
	Continued improvement after Ph1	1	Ph1+1yr	RR	0.32 (0.19, 0.55)	<0.001	-	Probably less likely to further improve after Tx.
	Extraction need for Ph2	1	Ph2	RR	0.81 (0.33, 2.01)	0.647	-	There may be little or no difference in the need for tooth extractions for Ph2.
	Overall Tx duration in months (Ph1+Ph2)	1	Ph1+Ph2	MD	14.40 (8.91, 19.89)	<0.001	-	Probably increases overall Tx duration.
	Patient compliance after Ph2	1	after Ph2	MD	0.44 (0.10, 0.78)	0.012	-	Probably increased compliance after Ph2.
	Patient compliance for Ph2	1	Ph2	MD	0.66 (0.38, 0.94)	<0.001	-	Probably increased compliance for Ph2.
	Patients in PAR-category <5 (ideal)	1	Ph2	RR	1.14 (0.74, 1.77)	0.547	-	There may be little or no difference in the probability to have ideal occlusion according to PAR after Ph2.
	Patients in PAR-category 6-10 (good)	1	Ph2	RR	1.03 (0.40, 2.63)	0.953	-	There may be little or no difference in the probability to have good occlusion according to PAR after Ph2.
	Ph2 Tx duration in months (with interim Tx)	2	Ph2	MD	-7.13 (-12.22, -2.04)	0.006	-	Probably decreases the duration of Ph2 Tx (with the interim Tx).
	Ph2 Tx duration in months (without interim Tx)	1	Ph2	MD	1.80 (-2.16, 5.76)	0.373	-	May increase the duration of Ph2 Tx (without the interim Tx).
	Relapse after Ph1	1	Ph1+1yr	RR	2.40 (1.44, 3.99)	0.001	-	Probably increased relapse after Ph1.
	SNB	11	Ph1	MD	-0.20 (-0.47, 0.06)	0.130	44%	There may be little or no difference in the SNB angle after Ph1.
	SNB	1	Ph2	MD	-0.02 (-0.14, 0.10)	0.745	-	There may be little or no difference in the SNB angle after Ph2.
	Surgical Tx need for Ph2	1	Ph2	RR	0.47 (0.24, 0.93)	0.030	-	Probably decreases the need fot surgical Tx for Ph2.
	Tx difficulty for Ph2	1	after Ph1	MD	-0.91 (-1.23, -0.59)	<0.001	-	Probably decreased difficult for Ph2.
	Tx priority for Ph2	1	after Ph1	MD	-0.28 (-0.41, -0.15)	<0.001	-	Probably decreased priority for Ph2.
	Tx success after Ph1	1	Ph1	RR	8.19 (3.73, 17.98)	<0.001	-	Probably increases Tx success for Ph1.
	Tx success after Ph1	1	Ph1+1yr	RR	3.95 (2.14, 7.31)	<0.001	-	Probably increases Tx success for Ph1.
	Tx success after Ph1: hyperdivergent	1	Ph1+1yr	RR	3.36 (1.59, 7.11)	0.001	-	Probably increases Tx success for Ph1.
	Tx success after Ph1: hypodivergent	1	Ph1+1yr	RR	10.83 (0.66, 177.02)	0.095	-	May increase Tx success for Ph1.
	Tx success after Ph1: mandibular prognathism	1	Ph1+1yr	RR	6.89 (1.73, 27.50)	0.006	-	Probably increases Tx success for Ph1.
	Tx success after Ph1: mandibular retrognathism	1	Ph1+1yr	RR	2.84 (1.14, 7.09)	0.025	-	Probably increases Tx success for Ph1.

	Tx success after Ph1: maxillary prognathism	1	Ph1+1yr	RR	3.23 (1.30, 8.05)	0.012	-	Probably increases Tx success for Ph1.
	Tx success after Ph1: maxillary retrognathism	1	Ph1+1yr	RR	5.50 (1.40, 21.62)	0.015	-	Probably increases Tx success for Ph1.
Adverse effects								
	Children with at least 1 incisor with severe EARR	1	Ph2+Ret	RR	0.60 (0.24, 1.52)	0.282	-	May decreases the incidence of severe EARR during and after Ph2.
	Incidence of dental trauma during Ph1	2	Ph1	RR	0.80 (0.42, 1.49)	0.475		There may be little or no difference in dental trauma during Ph1.
	Incidence of dental trauma during Ph1; category non-minor	1	Ph1	RR	0.61 (0.06, 6.53)	0.683	-	May decreases the incidence of non-minor dental trauma during Ph1.
	Incidence of dental trauma during Ph1+Ph2	1	Ph1+Ph2	RR	0.68 (0.39, 1.17)	0.159	-	May slightly decrease the overall incidence of new dental trauma during the whole Tx (Ph1 and Ph2).
	Incidence of dental trauma during Ph2	2	Ph2	RR	0.34 (0.14, 0.80)	0.014	0%	Probably decreases the incidence of dental trauma during Ph2.
	Incidence of dental trauma during Ph2; category non-minor	1	Ph2	RR	0.37 (0.02, 8.84)	0.538	-	May decrease the incidence of non-minor dental trauma after Ph2.
	TMJ muscle pain	1	Ph1	RR	0.79 (0.55, 1.15)	0.215	-	There may be little or no difference in muscle pain during Ph1.
	TMJ muscle pain; initially no	1	Ph1	RR	0.64 (0.35, 1.16)	0.139	-	May decrease the incidence of muscle pain during Ph1.
	TMJ muscle pain; initially yes	1	Ph1	RR	1.02 (0.68, 1.54)	0.917	-	There may be little or no effect on existing muscle pain during Ph1.
	TMJ pain	1	Ph1	RR	0.70 (0.42, 1.15)	0.160	-	There may be little or no difference in TMJ pain during Ph1.
	TMJ pain; initially no	1	Ph1	RR	0.54 (0.23, 1.25)	0.149	-	May decrease the incidence of new TMJ pain during Ph1.
	TMJ pain; initially yes	1	Ph1	RR	0.85 (0.48, 1.49)	0.561	-	There may be little or no effect on existing TMJ pain during Ph1.
	TMJ sound	1	Ph1	RR	1.09 (0.43, 2.74)	0.861	-	There may be little or no difference in TMJ sound during Ph1.
	TMJ sound; initially no	1	Ph1	RR	1.15 (0.32, 4.06)	0.831	-	There may be little or no difference in TMJ sound during Ph1.
	TMJ sound; initially yes	1	Ph1	RR	0.53 (0.21, 1.38)	0.193	-	May eliminate the TMJ sounds after Ph1 in patients that initially had.

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Supplementary Table 7. Subgroup analyses for the meta-analysis of the annualized difference headgear minus control regarding various patient- or treatment-related factors. Coeff, meta-regression coefficient; CI, confidence interval; M/F, male/female; MD, mean difference; SMD, standardized mean difference.

			SNA				**SNNL & FHNL**				**CoA & NperpA**		
			n	**Coeff (95% CI)**	**P**		**n**	**Coeff (95% CI)**	**P**		**n**	**Coeff (95% CI)**	**P**
Baseline		Age	13	-0.07 (-0.53, 0.39)	0.742		12	-0.13 (-0.74, 0.49)	0.655		8	0.01 (-0.45, 0.47)	0.959
		M/F ratio	13	-0.92 (-7.47, 5.64)	0.763		11	-2.25 (-13.36, 8.86)	0.657		8	-3.69 (-10.23, 2.85)	0.217
		Baseline SNA	12	0.16 (-0.10, 0.42)	0.211		10	-0.04 (-0.31, 0.24)	0.777		8	0.02 (-0.25, 0.28)	0.890
		Baseline SN-NL	8	-0.34 (-0.86, 0.18)	0.156		8	0.06 (-0.47, 0.59)	0.793		4	-	-
		Baseline 1s-NL	4	-	-		4	-	-		1	-	-
Treatment factors			**n**	**Coeff (95% CI)**	**P**		**n**	**Coeff (95% CI)**	**P**		**n**	**Coeff (95% CI)**	**P**
	Force magnitude		13	-0.00 (-0.01, 0.01)	0.957		12	0.01 (-0.01, 0.02)	0.312		9	0.00 (-0.01, 0.01)	0.934
			n	**MD (95% CI)**	**P**		**n**	**SMD (95% CI)**	**P**		**n**	**SMD (95% CI)**	**P**
	Force direction	High-pull	7	-1.49 (-2.28, -0.70)	0.824		7	0.11 (-0.30, 0.51)	0.267		6	-0.68 (-1.08, -0.28)	0.520
		Cervical	3	-1.85 (-3.14, -0.56)			4	1.50 (-0.26, 3.27)			-	-	
		Combination	3	-1.73 (-2.68, -0.79)			1	0.87 (0.31, 1.43)			3	-0.39 (-0.68, -0.11)	
	Appliance	Bands	7	-1.55 (-2.17, -0.93)	0.614		8	0.72 (-0.02, 1.46)	0.501		4	-0.47 (-0.90, -0.04)	0.689
		Biteplane	6	-1.81 (-2.80, -0.83)			5	0.19 (-0.12, 0.51)			5	-0.69 (-1.13, -0.24)	

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Supplementary Table 8. Two-level explorative analysis of factors associated with the treatment induced annualized SNA change in the headgear patients. Regressions are run within each of the three studies with raw data, followed by a random effects meta-analysis across studies of the effect of each factor on the annualized SNA change (regression coefficient). CI, confidence interval.

Factor	Studies	Patients	Pooled coefficient	95% CI	P	I^2	What happens
Age	3	90	0.01	-0.03, 0.05	0.735	0%	Little or no effect of initial patient age on SNA change.
Male	3	90	0.21	-0.69, 1.11	0.645	35%	Little or no effect of patient sex on SNA change.
Baseline SNA	3	90	-0.18	-0.25, -0.10	<0.001	0%	Patients with greater initial SNA angle experience a greater annual reduction in SNA with headgear.
Baseline ML inclination*	3	90	0.15	-0.22, 0.51	0.440	52%	Little or no effect of vertical pattern on SNA change.

*Standardized coefficients calculated and pooled as different variables were measured in the three studies (2 studies with the SN-ML angle and 1 study with the FH-ML angle).

Supplementary Table 9. Stratified meta-analyses of the headgear minus control annualized SNA change according to the baseline SNA angle from the three studies that provided raw data. Patients within each study are selected according to their SNA, and the effects are calculated anew, before pooling them across studies. MD, mean difference; CI, confidence interval.

Baseline SNA category	Studies	Patients	MD	95% CI	P	I^2	What happens
Any SNA values	3	161	-0.83	-1.23, -0.44	<0.001	0%	The therapeutic effects of headgear (annual reduction in SNA compared to no treatment) increase as the initial SNA increases.
SNA>82	3	78	-1.16	-2.07, -0.24	0.013	37%	
SNA>84	3	50	-1.34	-2.52, -0.17	0.025	22%	
SNA>86	3	31	-2.06	-3.91, -0.22	0.029	96%	

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Supplementary Table 10. Details of the GRADE assessment for each domain. CI, confidence interval; TMJ, temporomandibular joint; PAR, peer assessment rating; Ph1, phase 1 (headgear treatment/observation); Ph2, phase 2 (fixed appliance treatment following headgear treatment/ observation).

Outcome	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication bias	Large Effect	Dose Response	Residual Confounding
SNA angle	Starts from "low", due to the inclusion of non-randomized studies. Downgraded further by one point due to serious limitations (high risk of bias)	High heterogeneity; confidence regarding decision unaffected; heterogeneity affects just the precision of the estimate	Directly relevant	Adequate sample	Safe	No reason to rate up	Dose response relation possibly seeen. No upgrading, due to existing risk of bias	Cannot be ruled out
Inclination of NL	Starts from "low", due to the inclusion of non-randomized studies. Downgraded further by one point due to serious limitations (high risk of bias)	High heterogeneity, which could not be explained by subgroup analysis, while our confidence regarding decision is affected by it (trials on both sides of the forest plot)	Directly relevant	Adequate sample	Downgrade by one; no sign of publication, but signs of reporting bias identified. Imprecise studies tend to overestimate the results; downgraded by one for imprecision	Large effect magnitude; however no rating up due existing concerns regarding risk of bias and imprecision	No dose response relation assessment	Cannot be ruled out
Sagittal position of A point	Starts from "low", due to the inclusion of non-randomized studies. Downgraded further by one point due to serious limitations (high risk of bias)	High heterogeneity, which could not be explained by subgroup analysis, while our confidence regarding decision is affected by it (trials on both sides of the forest plot)	Directly relevant	Adequate sample	No evidence of bias	No reason to rate up	No dose response relation assessment	Cannot be ruled out
Nasolabial angle	Starts from "low", due to the inclusion of non-randomized studies. Downgraded further by one point due to serious limitations (high risk of bias)	Low heterogeneity; no reason to downgrade	Directly relevant	Adequate sample	Safe	No reason to rate up	No dose response relation assessment	Cannot be ruled out
PAR reduction	Downgraded by one point due to high risk of bias	No assessment of inconsistency possible	Directly relevant	Adequate sample	Safe	No reason to rate up	No dose response relation assessment	Cannot be ruled out
New incisor trauma (Ph2)	Downgraded by one point due to high risk of bias	Low heterogeneity; no reason to downgrade	Directly relevant	Adequate sample	Safe	No reason to rate up	No dose response relation assessment	Cannot be ruled out
New incisor trauma (Ph1+Ph2)	Downgraded by one point due to high risk of bias	Low heterogeneity; no reason to downgrade	Directly relevant	Inadequate sample; the 95% CI includes both the null effect and large effect values, which indicates imprecision	Safe	No reason to rate up	No dose response relation assessment	Cannot be ruled out

New TMJ pain	Downgraded by one point due to high risk of bias	No assessment of inconsistency possible	Directly relevant	Inadequate sample; the 95% CI includes both the null effect and large effect values, which indicates imprecision	Safe	No reason to rate up	No dose response relation assessment	Cannot be ruled out
Existing TMJ pain	Downgraded by one point due to high risk of bias	No assessment of inconsistency possible	Directly relevant	Inadequate sample; the 95% CI includes both the null effect and large effect values, which indicates imprecision	Safe	No reason to rate up	No dose response relation assessment	Cannot be ruled out

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Supplementary Table 11. Results of the sensitivity analyses. Coeff, coefficient; CI, confidence interval; RCT, randomized controlled trial; SMD, standardized mean difference.

	SNA				SNNL & FHNL		
	n	**Coeff (95% CI)**	**P**		**n**	**Coeff (95% CI)**	**P**
Sensitivity analyses							
RCT vs non-RCT	12	0.53 (-0.83, 1.90)	0.406		12	-1.04 (-3.10, 1.03)	0.290
Regression-based adjusted vs provided unadjusted data	12	0.94 (-0.30, 2.18)	0.122		12	-1.13 (-2.82, 0.56)	0.167
SN-NL- vs FH-NL-based SMD	-	-	-		12	-1.18 (-2.88, 0.52)	0.152

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Supplementary Table 12. Results of the sensitivity analyses. CI, confidence interval; MD, mean difference; RCT, randomized controlled trial; SMD, standardized mean difference.

	Original GRADE			Sensitivity analysis		
Outcomes no of participants (studies)	**Relative effects (95% CI)**	**Quality of the evidence (GRADE)**	**Changes performed**	**Relative effects (95% CI)**	**Quality of the evidence (GRADE)**	**What happens**
SNA angle 607 patients (12 studies)	MD -1.63 (-2.20 to -1.06)	⊖⊖⊖⊖ very low[a] risk of bias	• Excluded 6 non-RCTs • Used for 3 non-RCTs adjusted data for age, sex, and baseline SNA	MD -1.01 (-1.25, -0.77)	⊕⊕⊕⊕ high[d]	Probably decreases the SNA angle
SN-NL & FH-NL angle 667 patients (12 studies)	SMD 0.54 (0.09 to 1.00)	⊖⊖⊖⊖ very low[a,b,c] risk of bias, inconsistency, and reporting bias	• Excluded 7 non-RCTs • Used for 3 non-RCTs adjusted data for age, sex, and baseline SNA	SMD -0.23 (-0.55, 0.08)	⊕⊖⊖⊖ low[e,f,g] risk of bias, inconsistency, and imprecision	The effect on the inclination of the maxilla cannot be robustly assessed

[a] Starts from “low”, due to the vast inclusion of non-randomized studies. Further downgraded by one for high risk of bias in most studies.

[b] High heterogeneity, which could not be explained by subgroup analysis, while our confidence regarding decision is affected by it (trials on both sides of the forest plot).

[c] Signs of reporting bias (small-study effects) identified through Egger test. Small/imprecise studies tend to report greater treatment effects for headgear.

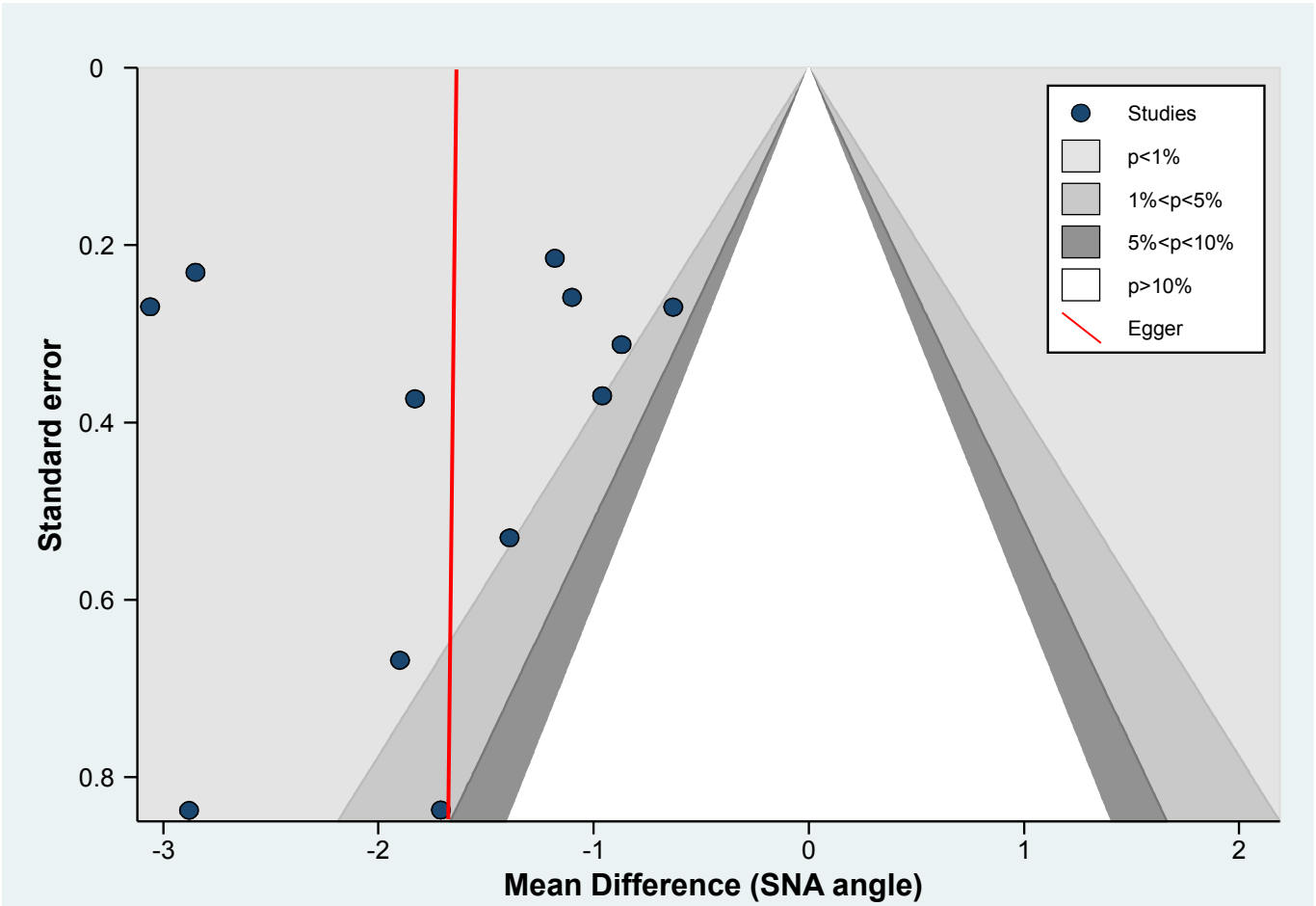
[d] Upgraded by one for dose-response effect of the headgear effectiveness (increased maxillary growth inhibition with increased baseline maxillary prognathism) and for absence of confounding (estimates adjusted for baseline SNA, change in maxillary inclination, and change in inclination of the upper incisors were similar to unadjusted estimates. The adjusted estimates from the 3 non-randomized studies were judged to be adequately protected against bias.

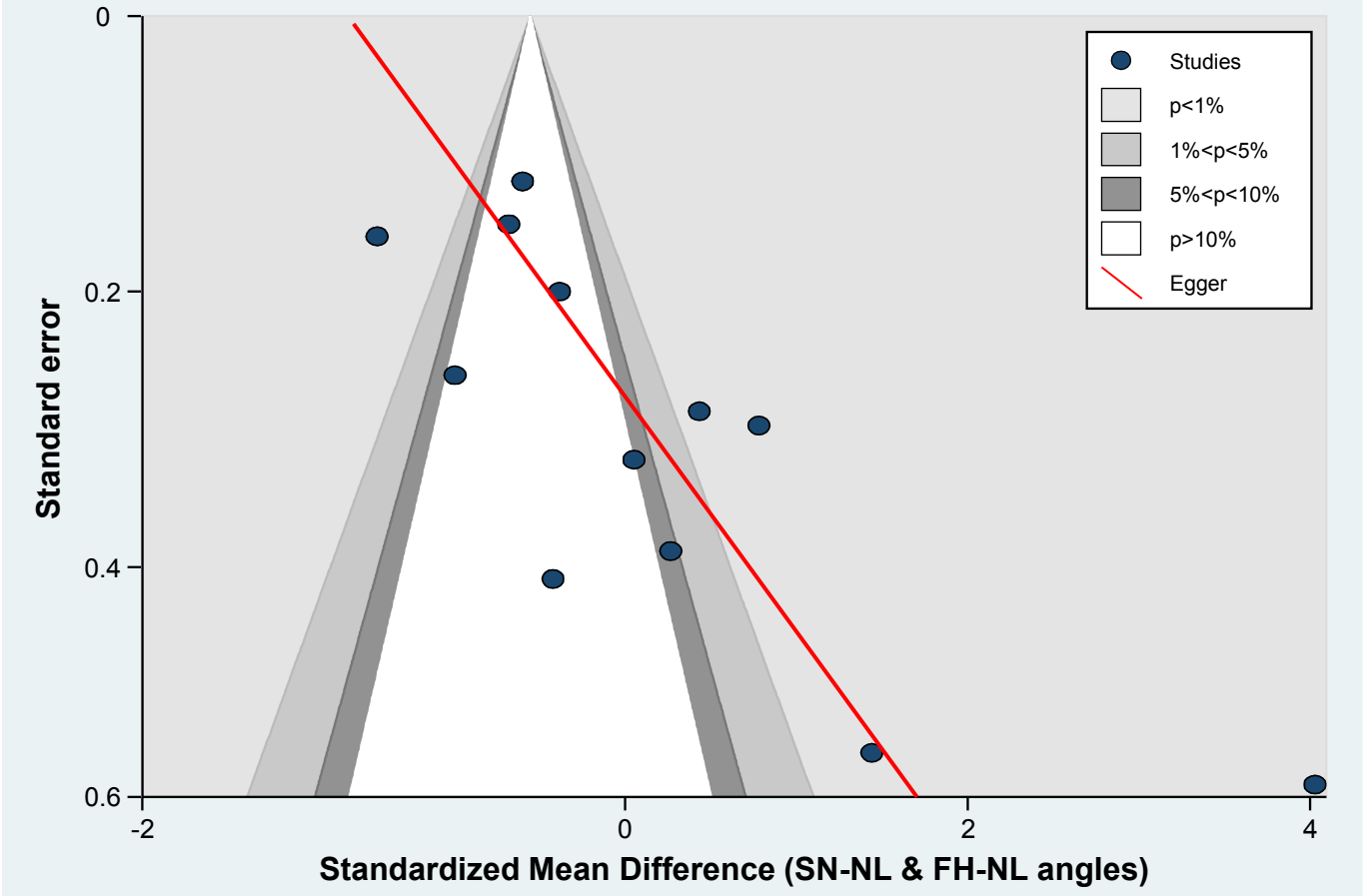
[e] Downgraded by one point for high risk of bias in included RCTs.

[f] Downgraded by one point for high heterogeneity (I^2=77%; 95% uncertainty interval= 21% to 89%).

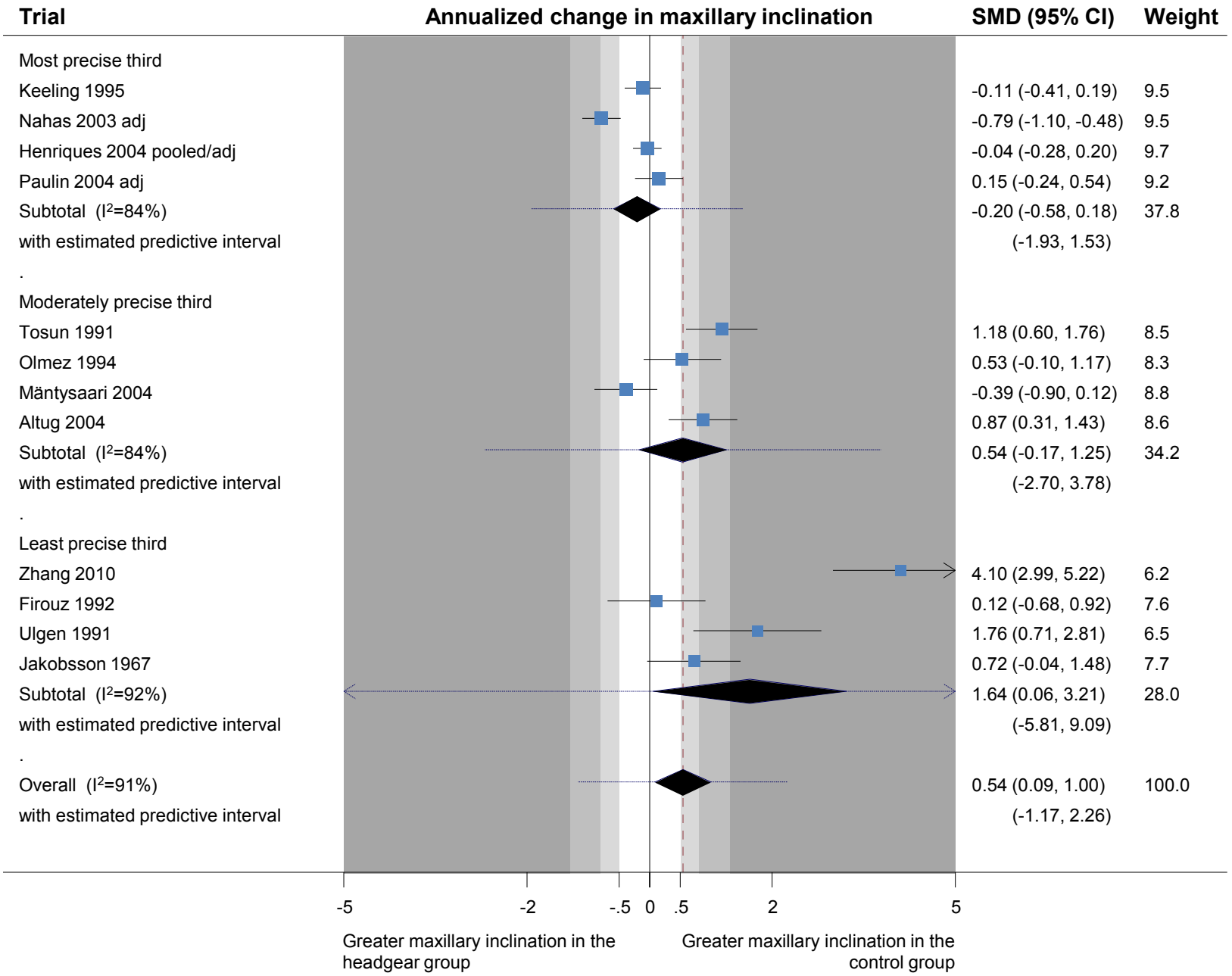
[g] Downgraded by one point imprecision, as the 95% CI includes both the considerable effect of SMD=0.5 and crosses the value of no effect.

Supplementary Figure 1. Contour-enhanced funnel plots for the assessment of reporting biases (including small-study effects and the possibility of publication bias).





Supplementary Figure 2. Subgroup meta-analysis of the SN-NL & FH-NL inclination change according to study precision. SMD, standardized mean difference; CI, confidence interval; adj, adjusted for confounding.



Supplementary Figure 3. Explorative analysis of the influence of maxillary inclination and the labial inclination of the upper incisors on the measured SNA change. MD, mean difference; CI, confidence interval; PrI, prediction interval.